Environment Canada Environnement Canada

20351141 VOL ISS 8 840600
EXC # 001

<REPORT> CC

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NEW CHEMICALS LEGISLATION
IN
OECD MEMBER STATES:

A Review of Notification Requirements

by

Peter Strahlendorf

Prepared under contract to the Commercial Chemicals Branch, Environmental Protection Service, Environment Canada.

CC-8
June, 1984

Box 625, Stn. Q
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NEW CHEMICALS LEGISLATION
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A REVIEW OF NOTIFICATION REQUIREMENTS

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CC-8
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ABSTRACT

The legislative or administrative mechanisms adopted by the national governments of the member states of the Organization for Economic Cooperation and Development (OECD) to control new industrial chemicals have been reviewed. The report outlines the activities of the OECD itself in the area of chemical control. The implementation of the Sixth Amendment in the European Economic Community Member States has been examined. The final notification rules for new chemicals established in 1983 under the United States Toxic Substances Control Act have been compared with the notification system directed by the Sixth Amendment.

ACRONYMS

ACOIN	Australian Core Inventory of Chemical Substances
AEC	Australian Environment Council
AICS	Australian Inventory of Chemical Substances
BAU	Federal Office for Occupational and Safety Policy (FRG)
BIAC	Business and Industry Advisory Committee (Europe)
CAS	Chemical Abstract Service
CCPA	Canadian Chemical Producers Association
CEC	Commission of the European Community
CELA	Canadian Environmental Law Association
CELRF	Canadian Environmental Law Research Foundation
DIG	Data Interpretation Guide (OECD)
ECOIN	European Core Inventory
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency (U.S.)
FCIO	Fachverband de Chemischen Industrie Osterreichs (Austria)
FOIA	Freedom of Information Act (U.S.)
FR	Federal Register (U.S.)
FRG	Federal Republic of Germany
GATT	General Agreement on Tariffs and Trade
GLP	Good Laboratory Practice (OECD)
IRPTC	International Register of Potentially Toxic Chemicals
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
MAD	Mutual Acceptance of Data (OECD)
MHW	Ministry of Health and Welfare (Japan)
MITI	Ministry of International Trade and Industry (Japan)
MPD	Minimum Pre-Marketing Set of Data (OECD)
NAEP	National Agency of Environmental Protection (Denmark)
OECD	Organization for Economic Co-operation and Development
OTA	Office of Technology Assessment (U.S.)
PCB	Polychlorinated Biphenyls
PMN	Pre-Manufacturing Notice (U.S.)
SNUR	Significant New Use Rule (U.S.)
TSCA	Toxic Substances Control Act (U.S.)
TUAC	Trade Union Advisory Committee (Europe)

ACKNOWLEDGEMENTS

The preparation of this report was assisted by on-going advice from Ruth Demayo of Environment Canada. Individuals who kindly provided information were Toby Vigod of the Canadian Environmental Law Association, Dell Higgie of the New Zealand Embassy in Ottawa, Rod Holsgrove of the Australian Environment Council, Blake Biles of the Washington law firm of Jones, Day, Reavis & Pogue, Susan Bofinger of the Chemical Manufacturers Association in Washington, and Margaret Young of the Parliamentary Library in Ottawa. David Rendeiro translated the relevant Luxembourg legislation. The staff of Government Institutes Inc. in Rockville, Maryland and the Bureau of National Affairs and the Environmental Protection Agency in Washington were helpful in advising what information was readily available in the international literature (and perhaps more importantly) what was not. The staff of the Ontario Ministry of Labour Library and the University of Toronto Law Library and Science and Medicine Library were particularly helpful. Dr. Bernhard Broecker, of Hoechst Aktiengesellschaft, Frankfurt, kindly reviewed the section on Germany.

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INTRODUCTION

This report is a review of the laws and guidelines in effect in OECD member states which relate to "new chemical" control. This report is specifically concerned with those legal mechanisms requiring the chemical industry to submit information to government authorities before engaging in chemical trade activities.

Traditional laws regulating chemicals have tended to concentrate on the emission of specific chemical pollutants into specific environmental media or have required licencing or registration for recognized biologically active groups of chemicals such as drugs and pesticides. The type of legislation analyzed in this report is of a very different nature. New chemical control legislation is "preventative". It provides a method of identifying and evaluating chemicals which might be harmful to humans and/or the environment before they are released. The new type of legislation casts a wider net than traditional environmental laws. All new chemicals (with precisely defined exemptions) must pass through a notification and judgment process. Each new chemical must be evaluated in order to determine its hazardous characteristics before it can be manufactured or marketed freely. This evaluation process provides an opportunity to impose conditions on the manufacture or marketing of the chemical.

A number of the member states of the OECD do not have specific legislation for evaluating new chemicals. Instead they often have legislation requiring a permit or a licence for the manufacture or importing of the more hazardous existing chemicals. Such legislation has been reviewed in this report in order to determine if notification and evaluation schemes are included and, if so, how they operate.

Societies differ in their legal, political and cultural traditions and institutions. Legislation cannot normally be transplanted between different jurisdictions without adverse effect. What use is a survey of national legislation? Comparative legal analysis is helpful in identifying trends, policy issues and practical legal problems and their attempted solutions (successful or not).

What is the background to new chemical control? It is predicted that between 1950 and 1985 the western world's production of organic chemicals will have increased 36 times to

250 million tons (1). Estimates of the production of chemicals worldwide ranges from $300 billion to over $470 billion (2) a year. $100 billion worth of chemicals is traded between nations each year (3). Today there are about 70,000 chemicals being marketed out of a universe of 4 million known chemicals. How many "new" chemicals go on the market every year? Estimates vary from 200 to 2,000 (4).

In the United States chemical sales totaled $64.9 billion in 1983 with 77% of those sales belonging to the top ten chemical companies (5). Canadian production of all chemicals and chemical products is about $12.7 billion. An additional $4 billion of chemicals is imported into the country. About $3.64 billion of the $12.7 billion production is exported from Canada (6).

A recent study has confirmed how little is known about existing chemicals (7). Of the 65,725 substances regulated or inventoried by the EPA and the Food & Drug Administration, about 74% are industrial or commercial chemicals not described as pesticides, cosmetics, drugs or food additives. About 79% of these industrial chemicals have no available toxicity data whatsoever.

Attempting to test and screen existing chemicals for their hazard potential would be an enormous task. In varying degrees some countries have begun to inventory the more common and/or the more hazardous chemicals in use in their industries. Such "poison lists" or "hazardous substances registers" frequently contain a minimal amount of required information because, for practical reasons when listing large numbers of chemicals, the

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(1) Rehbinder (1980).

(2) Slater (1983) and unpublished OECD documents dated March, 1983 provided by Environment Canada.

(3) Slater (1983).

(4) Rehbinder (1980).

(5) Storck (1984).

(6) CCPA (1983); see also Anderson (1983).

(7) Ember (1984) in reference to Toxicity Testing: Strategies to Determine Needs & Priorities, Washington: National Academy Press.

"lowest common denominator" of available data is used. Where testing is required, it is usually for a small number of the more readily identified extremely hazardous chemicals. However, in other jurisdictions around the world it has been decided to focus resources on new chemicals coming onto the market rather than launch a massive program to evaluate all existing chemicals.

There are provisions in the Canadian Environmental Contaminants Act (8) which require information to be submitted to the government, if requested (9), as well as a notice provision in the case of the manufacture or import of a chemical compound in excess of 500 kg/year for the first time (10). A number of critiques have been published concerning Canada's efforts in the area of regulating new chemicals (11).

It is not the purpose of this report to review the Canadian legislation or to make recommendations for reform. The purpose of this report is to clarify the characteristics of new chemical control mechanisms in other OECD member states. In this regard particular attention is paid to the activities of the OECD chemical control program and to the implementation of the Sixth Amendment in EEC member states. The characteristics of the American system are particularly important given the size of the U.S. chemical industry and the close economic relationship between the U.S. and Canada.

Hopefully the challenges and opportunities in new chemical control experienced by other nations will be instructive in the Canadian context.

The limitations of this review must be noted. Due to time constraints the competent government authorities in each of the 24 countries covered by this report could not be individually contacted. Therefore, information used herein was that provided by Environment Canada and others on short notice, as well as what was readily available in the international literature. Obtaining copies in English of the laws and regulations of other countries is difficult. There is frequently a time lag between the enactment of a law in

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(8) Environmental Contaminants Act, S.C. 1974-75-76, c.72.

(9) Section 3.

(10) Subsection 4(6).

(11) Castrilli (1982), Demayo (1983), Neff (1983), CELA/CELRF (1981).

Italian, French or German, for example, and the issuance of an official version in English. Often unofficial English versions are available from those directly involved in the chemical industry but these translations must be used with caution as they are frequently imprecise. Many laws appear in such publications as the International Environment Reporter, the International Digest of Health Legislation, the IRPTC Bulletin, International Legal Materials, and others but again they are often 2 to 3 years behind in their reporting and in the case of some publications edited or condensed versions of law are reproduced (at times critical provisions are missing).

1.1 ISSUES IN CHEMICAL CONTROL

New chemical legislation raises many questions. The following list of questions has been drawn from new chemical control experience in the EEC, the OECD chemical control program, the U.S. development of TSCA and the experience of many of the non-EEC countries in the OECD. The list is certainly not exhaustive. Many of the questions are dependent on previous choices having been made. In some countries political, legal, economic or social conditions prevent some of the questions from being raised at all.

Nevertheless, the following questions outline many of the critical issues in modern chemical control. The issues have been addressed differently in different jurisdiction or are in the process of being considered. Most of them will have to be addressed in Canada in the very near future.

> What should be the overall philosophy of risk or hazard assessment embodied in new chemical legislation? What degree of scientific confidence should be the standard for decision-making?
>
> Should knowledge always precede action or should the public's "chemophobia" be taken into account? In other words, to what extent should the principle of reverse onus be present in new chemical legislation? Should the government be able to take action upon "suspicion"?
>
> Should a notification system collect data for the sake of having it just in case a problem arises in the future, or should each type of information submitted to the government be justified for a specific purpose?
>
> How should the legislation be coordinated with that of other jurisdictions? A major trading partner's national legislation for example?
>
> How closely should the recommendations of international groups be followed for the purpose of harmonization of laws?

Through international organizations, many Third World countries, which often lack the infrastructure to control chemicals, are demanding that the industrial nations which export chemicals ensure that they are not subject to hazards from exported chemicals which the people of the exporting nation would not accept themselves. To what extent should such concerns be reflected if at all in new chemical legislation?

It is not only Third World countries which are concerned with the issue. Should chemicals banned in an exporter's country be automatically banned in the importing country or should they be assessed more rigorously?

Should new chemical legislation require that imported chemicals be accompanied with evidence or proof of how the chemical is treated in the country of manufacture or export?

Is it impractical to demand that all information submitted to another government for a chemical also be submitted to the government of the importing nation? How could this be enforced?

How will the OECD MAD principle be applied? Aside from the acceptance of data, will risk assessment be accepted? How will the OECD principle of Mutual Recognition of Compliance with the GLP be applied?

Should new chemical legislation restrict itself to chemicals not already covered by pesticide or drug regulation, or should an omnibus statute be enacted - repealing other laws?

Can "old" legislation be amended or should new regulations (decrees/orders) be made under old legislation, or should a fresh legislative start be made?

Should new chemical legislation cover occupational health and safety concerns?

Should new chemical legislation include hazardous products? In Canada, for example, should the Hazardous Products Act be absorbed by new chemical legislation?

What is a "chemical"?

When is it a "new" chemical?

How should mixtures, formulations and preparations be treated? In other words, when does a chemical become something else?

How should consumer products containing or incorporating new chemicals be treated?

Are some types of chemicals never biologically active so that they should not be included in the meaning of "chemical"? (eg: polymers)

Should an inventory be made of existing chemicals so that anything not on the list is "new"?

What should the criteria be for entry into the inventory?

Should the inventory be updated with notified chemicals added to the list so that "new" chemicals become "old" - and no longer require notification?

Should some chemicals be excluded from regulation because they are made only in small quantities, or because they are used only in research or as reagents?

Should intermediate chemicals be covered by the legislation if they are never marketed and remain at or are used in the factory they were made in?

Should chemicals be exempt if they are solely for export?

How should by-products and impurities be handled?

Should there be an exemption for the test-marketing of new chemicals?

Should notification be given only after a specified quantity has been produced or put on the market?

Who should be responsible for notification? The manufacturer, importer, wholesaler, transporter?

Who is the "importer"? How should subsidiaries and agents be considered?

If pre-importing notification is not required should import notification be given? Should such notification be received by customs authorities?

If importers are treated differently from domestic manufacturers, will the new chemical legislation be seen as creating "non-tariff trade barriers"? Will this result in a violation of GATT? Will other countries penalize exports to their markets by imposing countervail duties?

What information should be included in the notification?

What flexibility should there be in the information requirements for notification? If information can be omitted or substituted, on what grounds should this be allowed? Scientific? Time? Cost? Should written justification for any omission or substitution be required?

Should data be required to be submitted during the notice review period?

Who should notification be sent to?

How should the notification authority be constituted? Should it be a bureaucratic section or division or should it be a semi-independent administrative Board or Tribunal? Should the notification authority be an inter-ministerial body?

Should the notification authority be constituted so that there is representation from manufacturer's associations, labour groups, consumer or environmental public interest groups, or provincial concerns?

When should notification be given, ie. what should trigger notification? Manufacturing? Marketing? Importing? Processing? Should the trigger be the act or the intention?

What tests should be done for new chemicals? Will the OECD MPD be adopted?

Who should do the tests?

Should the notification authority do some or all tests? Should it have the power to have independent institutes, universities or companies do testing on a contract basis? How can confidentiality be ensured in such a case?

Who should pay the cost of testing?

How can consistency in testing be guaranteed? Will the OECD GLP be adopted?

Should a chemical go freely onto the market unless a specific stop order is issued or should all chemicals be prevented from being marketed until they receive specific approval or "licence" to proceed?

How much responsibility should the notification authority take once it has "licenced" a chemical as "safe"?

If new chemical control is too detailed will the common law defence of "statutory authorization" arise?

Should the notification authority be required to approve or disapprove within a specified time from the date of notification?

Should the notification authority be allowed to request further information or tests? What limits should be placed on such powers?

What kinds of orders should the notification authority be able to make other than approval or disapproval? eg: conditions, marketing restrictions, production restrictions, special labelling or handling requirements.

Should new chemical legislation include provision for the appeal from orders or decisions made by the notification authority? Should such appeals be made for all or for some types of decisions? Should appeals be to the court system or to an administrative tribunal which may have more scientific expertise?

How much of the information supplied should be confidential? Who decides? Should there be a maximum set of confidential information or should issues of confidentiality be subject to case by case discretion?

Should labour representatives be permitted access to confidential data under special security arrangements?

If the specific identity of a chemical is confidential how will other manufacturers know if their own new chemical is truly new? Does it matter if "new" means new for a particular manufacturer rather than absolutely new?

If other manufacturers wish to market the same chemical should they provide compensation to the first notifier for the latter's expenses in testing the chemical?

Who decides how much compensation is fair?

Should a time limit (eg: 5 years) be placed on how long submitted data may remain secret?

How will the OECD principles regarding the transfer of confidential data between countries be applied?

Is the government the "owner" of data submitted to it, or is the government the "trustee" of data - ownership remaining with the notifier? What are the implications of each of these?

Should the notification system be open-ended; that is, should further information be provided subsequent to notification?

What should trigger further submissions? Changes in quantity produced or imported? Changes in composition or purity? Advances in scientific knowledge and a concomitant change in assessment of a chemicals properties or its effects?

Should such further notification be on an automatic annual basis? Perhaps the notification authority should have a wide degree of discretion to decide when and what information is required?

Should the principle of "step sequence testing" be applied and if so, how?

Should the public participate in the process at all or any point through the notification process? If so, in what forum and with what information?

What penalties should accompany the duties and responsibilities of all parties in the system (including penalties for civil servants in breach of confidentiality requirements)?

Should the legislation impose both civil and criminal liability?

Should offences differentiate between negligent and wilful acts? Should offences differentiate between corporations and responsible individuals within corporations?

Should the concepts of "rectification", "toxic torts" or the defence of "due diligence" be expressly stated in the legislation?

1.2 THE EEC SIXTH AMENDMENT

This section of the report will cover some background issues before considering the Sixth Amendment itself. A consideration of the nature of the EEC as a legal entity, the nature of a Directive, and what effect a Directive of the EEC has on the national laws of Member States is in order. This review is important because non-Europeans frequently misunderstand issues involving the EEC because the EEC is a unique and novel entity; there is no similar entity in the experience of non-Europeans to compare it with.

What is the EEC?

The European Economic Community was created by the six original Member States in 1957 by the Treaty of Rome. The EEC is a supra-national layer of government, it is not an association such as the United Nations or the OECD. To illustrate, some provisions of EEC law penetrate the national law of Member States to the level of the individual, conferring rights to and imposing obligations on the individual (1).

What is the structure of the EEC?

a) Council of Ministers - is the legislative body of the EEC. The Council is made up of ministers from the governments of each of the Member States. The ministers change according to the issue. For environmental issues, the Ministers of the Environment (or equivalent title) attend the Council.

b) Commission of the European Community - is the civil service of the EEC. The Commission has 13 commissioners with one or two from each Member State. Their administrative staff of over 10,000 civil servants is organized in 20 directorates-general, each responsible to one of the commissioners.

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(1) This principle of "direct effect" was recognized by the European Court of Justice in Case 26/62, Van Gend en Loos v. Nederlandse Administratie der Belastingen, (1963) ECR 1.

c) European Parliament - is a consultative or advisory body which does not make law but comments on proposed legislation. It has restricted budgetary and dismissal powers. Recently, there has been a power struggle between the Parliament and the Council (2). Members are elected by citizens of each Member State.

d) Economic and Social Committee - a second advisory body consisting of representatives of local governments, industry, trade unions, consumer groups, farmers, etc. The 144 members of the Committee are appointed by the Council but serve in their personal capacities.

e) European Court of Justice - has jurisdiction over all matters relating to EEC law. It is the ultimate legal authority in the EEC (3).

How is EEC law made?

The Commission, which must consider only the interests of the EEC as a whole, proposes legislation. The Council either adopts or rejects the proposed legislation, it cannot amend it. Parliament and the Economic and the Social Committee have the opportunity to comment on all steps of the legislative process. The Court of Justice ensures that EEC actions conform with the treaties which form the EEC's constitution. The Court also ensures that Member States live up to their EEC obligations (4).

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(2) In February, 1984 the European Parliament endorsed a draft treaty designed to alter the balance of power in the EEC by giving Parliament greater powers of initiative and control. "European Parliament still lacks strong popular input", Toronto Globe & Mail, May 28, 1984, p. IB 11.

(3) The information on the structure of the EEC is drawn from: Price Waterhouse, Doing Business in the European Communities (1978); (Reference) Int'l Env. Rep. 131 : 0101 - 131 : 0102 (1983); Lesser (1983).

(4) Ibid.

Types of EEC legislation

EEC law is composed of "basic legislation", being treaties and protocols, and "secondary legislation", being Directives, Regulations and Decisions.
The treaties provide general obligations on Member States to ensure fulfillment of treaty objectives, secondary legislation requirements as well as an obligation not to take any measures which might jeopardize the aims of the treaties. Where EEC and national laws conflict, the treaties require that EEC law must prevail. This distinguishes the EEC from other international organizations Member States have given up part of their own legal sovereignty and have transferred it to a supra-national sovereign entity, the EEC. Some of the treaties have a "direct internal effect" on the national affairs of Member States (5).

The characteristics of the types of "secondary legislation" are as follows (6):

a) Regulations - are laws directly binding in Member States without further action by the national governments. Most regulations are made by the Commission and relate to agriculture.

b) Directives - are not laws themselves but are a form of legislative instrument proposed by the Commission, adopted by the Council and addressed to Member States. They require Member States, usually within a 2 year period, to incorporate the provisions of the Directive in national legislation. Directives are binding on Member States but on rare occasion may directly confer entitlements on persons within Member States. Over fifty Directives have been issued with respect to environmental matters. The Sixth Amendment relating to new chemical notification is one of these (7).

c) Decisions - are usually issued as a result of specific circumstances on a case-by-case basis. They are normally made by the Commission and may be addressed to Member

---

(5) See footnote (1).

(6) Price Waterhouse, Doing Business in the European Communities (1978).

(7) See Annex IV of Johnson (1983) for a list and description of EEC Directives on environmental matters.

States or persons within Member States. They have a similar effect as national case law.

Aside from the above "secondary legislation", both the Council and the Commission may issue Recommendations and Opinions, which are not legally binding but are very morally persuasive.

Effect of an EEC Directive

There are two fundamental principles of European Community law, briefly mentioned *supra*: 1) the principle of direct effect; and 2) the principle of primacy of Community law. Member States must ensure, if necessary by amending their constitutions, that these principles are respected (8). The latter principle is the more important one when considering the Sixth Amendment - the purpose of which is the harmonization of national laws.

Why is harmonization of national laws considered important in the EEC? One reason is that the preservation of the quality of life, in the case of environmental Directives, is an essential feature of a well-functioning common market. Second, in Member States where the national law is otherwise more strict than in other Member States, manufacturing costs will likely be higher. This is considered to be an undesirable distortion of competition in the common market.

The effect of a Directive is spelled out by Article 189 of the EEC Treaty:

> (a Directive) shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.

Article 100 of the EEC Treaty provides a general power of harmonization:

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(8) A brief review of these two principles is found in Dashwood (1983).

> The Council shall, acting unanimously on a proposal from the Commission, issue Directives for the approximation of such provisions laid down by law, regulation or administrative action in Member States as directly affect the establishment or functioning of the common market ...

As one authority has noted (9):

> Harmonising directives do not, therefore, lay down rules of uniform application but place the Member States under an obligation to amend existing law and/or practice, unless they already achieve the prescribed aim.
>
> It follows that the impact of harmonisation on national law may be to some extent disguised, especially if implementation is by a national measure that deals with other matters at the same time. The impact may also be uneven, because the Member States will implement harmonising directives with varying degrees of loyalty and efficiency.
>
> An important development is the recognition by the Court of Justice that, where a Member State has failed to implement a harmonising directive either properly or at all, and the date for implementation has passed, provisions in the directive that are unconditional and sufficiently precise may be invoked by individuals against the defaulting state in proceedings before a national court. Thus, for instance, a trader who has complied with the labelling requirements of a directive may resist a prosecution brought on the basis of unamended national legislation specifying different requirements.
>
> The rationale of the direct effect accorded to directives is that a Member State must not be allowed to rely as against an individual on its own failure to perform a Community obligation - an application of

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(9) Ibid., p. 162.

> the principle that no one should profit from his own wrong. Since by definition directives can only impose obligations on Member States, it seems to follow that a provision contained in a directive could not be enforced by one individual against another. The Court has not yet ruled explicitly on the point.

As will be seen in the review, infra, of the national legislation implementing the Sixth Amendment, the "choice of form and methods" given by Article 189 has resulted in considerable variety in new chemical notification systems developed by EEC Member States. In fact, the legislation of at least one country, Denmark, is in contradiction to the provisions of the Sixth Amendment and may result in a case before the European Court of Justice (10).

Development of the Sixth Amendment

The details of the historical development of the Sixth Amendment from the first Directive on the subject in 1967 to the sixth amendment of that Directive have been noted in a number of sources (11). The first Directive in 1967 (12) had two objectives, flowing from the Treaty of Rome, being: to protect the life and health of the general population (especially those who handle dangerous substances at work) and to achieve the free movement of these substances within the Community.

It is important to note that while the Sixth Amendment is referred to as an amendment of the 1967 Directive, the Sixth Amendment is a Directive and a complete document in itself (13).

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(10) See Anon., Chemical Week (1981).

(11) For example: Springborn (1982); Alston (1978).

(12) Council Directive of June 27, 1967 (67/548 EEC).

(13) The first and subsequent amendments of the 1967 Directive are as follows: Council Directive of March 13, 1969 (69/81/EEC); Council Directive of March 6, 1970 (70/189/EEC); Council Directive of March 22, 1971 (71/144/EEC); Council Directive of May 21, 1973 (73/146/EEC); Council Directive of June 24, 1975 (75/409/EEC) and Council Directive of September 18, 1979 (79/831/EEC) (the Sixth Amendment which was published in the Official Journal No. 259 of

Subsequent to the Sixth Amendment of September 18, 1979, a Commission Decision of May 11, 1981 (14) set out the criteria under which Member States are to provide information relating to the EEC inventory of existing chemical substances.

Overview of the Sixth Amendment

Articles 5-12 of the Sixth Amendment relate to the notification system. Article 13 refers to the inventory of existing substances. The remaining provisions relate primarily to packaging and labelling matters. Annex V sets out the methods for the determination of physico-chemical, toxicological and ecotoxicological properties, Annex VII contains the "base set" of data required to be notified and Annex VIII sets out addition information and tests required when the quantity of the chemical marketed reaches certain levels.

Status of Implementation

The Sixth Amendment required that Member States must implement its provisions by September 18, 1981. By 1984 apparently all Member States had developed implementing legislation except for Greece (although express confirmation of the enactment of final laws in the Netherlands and in Luxembourg has not been noted).

Purpose or Scope

The preamble of the Sixth Amendment states that its purpose is to "protect man and the environment against potential risks which could arise from the placing on the market of new substances". The preamble also refers to Article 100 of the Treaty of Rome indicating that harmonization of national laws so as to facilitate trade in a common market is also an objective.

October 15, 1979). There were two Commission Directives along the way which adapted the Annexes: Commission Directive of July 14, 1976 (76/907/EEC) and Commission Directive of January 30, 1979 (79/370/EEC).

(14) Commission Decision of May 11, 1981 (81/436/EEC).

Effective Date of Notification Requirement

Member States were required to have effective notification provisions in place by September 18, 1981. Not all did. This means the effective date varies among Member States. Until six months after publication of the inventory of existing chemical substances, the notification provisions apply to substances placed on the market after September 18, 1981. Six months after the publication of the inventory, the notification provisions apply to the substances not appearing in the inventory (15). The final inventory will probably not be published until 1985. This means that while notification systems will be operating before 1985, the form of the final system is not yet functioning.

Type of Notification

Notification must be given to a Member State's competent authority before a substance is "placed on the market" (16). This phrase is defined as "supplying or making available to third parties" and includes "importation into Community customs territory" (17). This system is referred to as a pre-marketing and pre-importing system.

Notification Time Period

Notification must be made "at the latest 45 days before the substance is placed on the market" (18).

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(15) Article 1, para. 4.

(16) Article 6, para. 1.

(17) Article 2, para. 1(e).

(18) Article 6, para. 1.

Responsibility for Notification

The manufacturer or importer of a notifiable substance is required to submit the notification (19). Neither "manufacturer" or "importer" is defined. Which party involved in an import transaction is the legal entity known as the "importer"?

Notification Authority

Member States "shall appoint the competent authority or authorities responsible for receiving" the notification (20). Note that this requirement allows considerable flexibility as to the nature of the competent authority in Member States. Evaluation functions may be split between or shared by several administrative bodies.

Chemicals to be Notified

The Sixth Amendment does not apply to (21):

(a) medicinal products and narcotics;
(b) radioactive substances;
(c) the carriage of dangerous substances;
(d) foodstuffs or feedingstuffs;
(e) waste material covered by other Directives;
(f) substances in transit under customs supervision provided they do not undergo any treatment;
(g) pesticides and fertilizers if they are already subject to equivalent notification procedures;
(h) other substances already subject to similar testing and notification requirements under existing Directives.

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(19) Ibid.

(20) Article 7, para. 1.

(21) Article 1, paras. 2 and 4(b) & (c).

This does not mean, however, that a Member State is prohibited from combining implementation of a new chemical notification system with an existing notification system, for example, pesticides.

The main notification provision refers to "substances". These are defined as "chemical elements and their compounds as they occur in the natural state or as produced by industry, including any additives required for the purpose of placing them on the market" (22). The main notification provision does not refer to preparations. However, a substance cannot be placed on the market on its own or in a preparation unless the substance has been notified (23). Thus, a notifiable substance in a preparation but not the preparation itself must be notified. But this means concern must be given to the composition of preparations. A "preparation" is a mixture or solution composed of two or more substances.

Currently, it is only those "substances" not marketed before September 18, 1981 which must be notified. Six months after the publication of the inventory of existing chemicals, only those substances not in the inventory must be notified (24). This provision means the notification system is for new substances. Since notified substances are not put on the inventory, "once new always new".

Total Exemptions

Notification is not required of the following:

(a) EEC exemption - if the substance has been notified to the competent authority of one of the Member States in accordance with the Sixth Amendment (25).

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(22) Article 2, para. 1(a).

(23) Article 5, para. 1.

(24) Article 1, para. 4.

(25) Article 5, para. 1.

(b) Polymer exemption - if the substance is a polymerizate, polycondensate or polyadduct, except those containing in combined form 2% or more of any monomer unmarketed before September 18, 1981 (26).

(c) Testing exemption - if the substance is for research and analysis purposes and is put on the market for the purpose of determining its properties in accordance with the Sixth Amendment (27).

(d) Research exemption - if the substance is placed on the market for research or analysis purposes in quantities of less than one tonne per year per manufacturer or importer and intended solely for laboratories (28).

If any of the substances covered by (b) - (d) above are "very toxic" or "toxic" (29), the manufacturer or importer must supply information to the competent authority regarding handling, storage, etc. precautions and emergency measures (30).

Partial Exemptions

(a) Quantity exemption - if the substance is placed on the market in quantities less than one tonne per year per manufacturer (31), provided that its identity, labelling data and quantity data are notified to the competent authority where the substances are placed on the market (32) and that any conditions imposed by such authority are complied with (33). If the substance is "very toxic" or "toxic" the data noted supra must be supplied.

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(26) Article 8, para. 1. Note that this does not refer to any monomer not on the inventory.

(27) Article 8, para. 1.

(28) Ibid.

(29) As determined by Article 16.

(30) Article 8, para. 3 in reference to the data in Annex VII, points 2.3, 2.4 and 2.5.

(31) Note that "importer" is not included.

(b) Ten year exemption - if the substance was originally notified at least ten years previously then the notifier need not supply the information for the technical dossier set out in Annex VII, except for points 1 and 2 of that Annex (identity, use, estimated production/imports, precautionary and emergency measures) (34).

(c) Partial research exemption - a one year exemption from notification applies to a substance if (35):

(i) it is placed on the market at the research and development stage;

(ii) with a limit number of "registered" customers;

(iii) in quantities limited to the purpose of research and development;

(iv) and if quantities of the substance amount to more than one tonne per year per manufacturer;

(v) provided the manufacturer announces its identity, labelling data, and quantity to the competent authority where the manufacture, research or development takes place;

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(32) Note that a manufacturer cannot use the EEC exemption: eg, he cannot manufacture a substance in Germany and market it in the U.K. without having notified the U.K. authority.

(33) Article 8, para. 1.

(34) Article 6, para. 3. To some extent this relieves the "once new always new" rule.

(35) Article 8, para. 1.

(vi) and if any conditions imposed by such competent authority are complied with;

(vii) and if the manufacturer gives an assurance that the substance or the preparation in which it is incorporated will be handled by customer's staff only, under controlled conditions, and will not be made available to the public;

(viii) provided that if the substance is "very toxic" or "toxic", the manufacturer or importer (36) must submit information to the competent authority regarding handling, storage, etc. precautions and emergency measures (37).

Inventory

The Sixth Amendment provides that the Commission will use information from Member States to draw up an inventory of substances on the Community market before September 18, 1981. The inventory is to contain the chemical name (preferably IUPAC), the CAS number and the common name or ISO abbreviation, if any (38).

As well, the Commission is to keep a list of all substances notified under the Sixth Amendment (39). The details concerning the inventory were to be developed at a later date (40).

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(36) But the main portion of the provision refers only to the "manufacturer".

(37) Article 8, para. 3; see footnote (30).

(38) Article 13, para. 1.

(39) Article 13, para. 2.

(40) Article 13, para. 3; Article 21.

The details were supplied through the Commission Decision of May 11, 1981 (41). The Decision changed the definition of "old" substance to those marketed in the EEC at any time between January 1, 1971 and September 18, 1981.

The inventory of chemical substances existing on the Community market by September 18, 1981 is referred to as EINECS (European Inventory of Existing Commercial Chemical Substances). The EINECS inventory is to be composed of a core inventory known as ECOIN (European Core Inventory) drawn up by the Commission by data at its disposal plus a list of substances which are declared to the Commission by the Member States as having been notified to their competent authorities (42).

The ECOIN list was published on March 31, 1982 (43). Any person resident in the EEC who had placed a substance on the market before September 18, 1981 could examine the ECOIN list. If that person's substance was not on the list he could make a declaration to the appropriate competent authority by December 31, 1982. The competent authority must have forwarded all such declarations to the Commission by March 31, 1983. At this time the ECOIN list plus the substances declared by March 31, 1983 as having been on the market by September 18, 1981, but missed by the ECOIN list, were added together to make up the EINECS inventory.

The English version of EINECS is expected to be published sometime in 1985 (44).

The notification requirements are complicated by the delay in the development of the EINECS inventory. Six months after EINECS is published in 1985, a person will need only check the EINECS inventory to see if a particular substance is on the inventory. If it is, then it is not a "new" substance and it need not be notified to a competent authority.

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(41) (81/437/EEC) Official Journal No. L 167/31 of 24.6.81; see CEC (1981) which contains declaration forms.

(42) Article 2 of the May 11, 1981 Decision.

(43) "Commission publishes core inventory of substances on market before deadline", (Current) Int'l Env. Rep. 5 : 140 (1982).

(44) "Environment Directorate recommends way to deal with issues of chemical identities", (Current) Int'l Env. Rep. 7 : 5 (1984).

Until such time, a person must determine if the substance had been marketed before September 18, 1981. Currently, this requires checking the ECOIN list. If it is on the list it is not "new", but is an existing substance. However, if it is not on the ECOIN list, it may still not be a "new" substance because it may have been declared by December 31, 1982 as having been missed by the drafters of the ECOIN list.

As of January, 1984 there was no way of knowing if a substance not on the ECOIN list will be on the EINECS inventory because the Commission had not made public the substances declared by December 31, 1982 (45).

Content of Notification

A notification shall include (46):

(a) a technical dossier:

(i) supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment,

(ii) and containing at least the information and results of the studies referred to in Annex VII,

(iii) together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them;

(b) a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged;

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(45) Ibid.

(46) Article 6, para. 1.

(c) the proposed classification and labelling of the substance in accordance with the Sixth Amendment;

(d) proposals for any recommended precautions relating to the safe use of the substance.

Testing Requirements

As mentioned above, the notification material must contain at least the Annex VII test results. Further tests may be required depending on the quantity of the substance put on the market, as discussed infra.

Mutual Acceptance of Data

The Sixth Amendment requires that when a Member State receives the notification material, or additional information (discussed infra), the competent authority shall send the Commission a copy of the dossier or a summary together with any relevant comments, and in the case of the additional information, the further tests required, reasons for their choice, and the assessment of their results (47). The Commission then forwards submitted material to other EEC Member States (48). Submitted material may be supplied to the Commission or other Member States in summary form but access to the original material shall be granted if requested (49).

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(47) Article 9.

(48) Article 10, para. 1.

(49) Article 12. Can the request be refused? Article 12 states that it is to be read in the context of Article 10, para. 2 which states that any Member State may directly consult with the competent authority of the Member State which received the original notification "on specific details of the data contained in the dossier" and then sets out a dispute resolution procedure. However, it is not clear that this allows a competent authority to refuse to divulge the original material and leave it to the Commission to resolve the dispute. It is more likely that the dispute resolution procedure applies only to disagreements over the Annex VIII program of studies. How can

There is a procedure for dealing with disputes between the original competent authority and those of other Member States if the latter do not agree with the exercise of discretion by the original competent authority with respect to additional tests and information required (50).

As mentioned, notification is not required if the substance has already been notified to the competent authority of another EEC Member State (51).

Flexibility in Notification Requirements

If a substance is listed in Annex I of the Sixth Amendment as a "dangerous substance", then the notifier need not submit the declaration, the proposed classification and the proposals for recommended precautions (52).

A notifier is required to inform the competent authority if particular circumstances change. One of these is a change in the annual or total quantities placed on the market by the notifier (53). Annex VIII to the Sixth Amendment contains details of additional information and tests which may be or are required to be submitted. These are normally contingent on certain levels of the marketed substance being reached.

When requested by the competent authority, a notifier may be required to submit data for the Level One tests on toxicological and ecotoxicological properties if the quantity marketed reaches a level of 10 tonnes per year or a total of 50 tonnes (54).

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another Member State consult on the "specific details" of the original material if it doesn't have access to the original material? If requests are refused they would be refused on questionable authority. This is an area of the Sixth Amendment system which could be clarified.

(50) Article 10, para. 2.

(51) Article 5, para. 1.

(52) Article 6, para. 3.

(53) Article 6, para. 4.

(54) Annex VIII.

If the quantities reach levels of 100/500 tonnes per year, the competent authority shall require the above tests to be done unless "in any particular case an alternative scientific study would be preferable" (55).

If the quantities reach levels of 1000/5000 tonnes per year, the competent authority shall draw up a program of tests to be carried out by the notifier (56). A list of further toxicological and ecotoxicological tests which must be covered by the program "unless there are strong reasons to the contrary, supported by evidence" is given in Level Two of Annex VIII.

The notifier is required to inform the competent authority of the results of any of the Annex VIII tests required to be done (57).

Further Testing/Follow-Up Measures

Other than the information on changes in quantity of the substance being placed on the market, the notifier is required to keep the competent authority informed of the following changed circumstances (58):

(a) new knowledge of the effects of the substance on man and/or the environment of which he may reasonably be expected to have become aware;

(b) new uses for which the substance is placed on the market of which he may reasonably be expected to have become aware;

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(55) Ibid.

(56) Ibid.

(57) Article 6, para. 5.

(58) Article 6, para. 4.

(c) any change in the properties resulting from a modification of the substance's composition (eg: degree of purity, impurities, additives).

A very important follow-up provision is that allowing the competent authority, if it can be shown to be necessary for the evaluation of the hazard, to (59):

(a) ask the notifier for further information and/or verification tests concerning the notified substance and this may include requesting the Annex VIII test results before the specified levels of marketed substance are reached;

(b) carry out such sampling as is necessary for control purposes;

(c) "take appropriate measures relating to safe use of a substance pending the introduction of Community provisions" (60).

Special Orders

Other than the follow-up measures discussed, supra, a Member State may provisionally prohibit the sale of a substance or subject it to special conditions in its territory if it has "detailed evidence" that the substance, although satisfying the Sixth Amendment, constitutes "a hazard for man or the environment by reason of its classification, packaging or labelling" (61).

However, the Member State must inform the Commission and other Member States if it takes such action and must give reasons.

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(59) Article 7, para. 1.

(60) It is not clear what this means.

(61) Article 23, para. 1.

There is a provision which states that a Member State may not, on grounds relating to notification, classification, packaging or labelling with the meaning of the Sixth Amendment, prohibit, restrict or impede the placing on the market of substances which comply with the Sixth Amendment (62).

Protection of Confidential Data

The Sixth Amendment expressly states that "Member States and the Commission shall ensure that any information concerning commercial exploitation or manufacturing is kept secret" (63).

There is also a provision that a notifier may request that commercially sensitive information, which might harm him industrially or commercially if disclosed, be kept secret from all persons other than the competent authorities and the Commission. Justification must be given (64).

A list of non-confidential data is expressly stated (65):

(a) the trade name of the substance;

(b) physico-chemical data;

(c) possible ways of rendering the substance harmless;

(d) the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests;

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(62) Article 22.

(63) Article 7, para. 3.

(64) Article 11, para. 1.

(65) Ibid.

(e) the recommended precautions relating to handling, storage, etc. and emergency measures.

If the notifier himself discloses previously confidential information he must inform the competent authority (66).

It is up to the competent authority whether information is confidential when so indicated by a notifier (67).

If a substance is not classified as "dangerous", a competent authority may request the Commission to include a substance on the Inventory under a code name if there is a confidentiality problem. But the substance may be on the Inventory in code form for no longer than 3 years (68).

Disclosure of Data and Proprietary Rights

If a substance has previously been notified, the competent authority may agree that a subsequent notifier of that substance may, for the purposes of the technical dossier, refer to the results of the studies carried out by one or more previous notifiers, provided the latter have given their agreement in writing (69).

As mentioned supra, the competent authority must provide submitted material or a summary of it to other Member States and the Commission. In such cases they must keep confidential information secret (70). Confidential information can only be given to other Member States if it is given to a competent authority appointed under the Sixth Amendment. However, if administrative or legal proceedings involving sanctions are undertaken for the purpose of controlling substances placed on the market, confidential data may be divulged to persons directly involved in such proceedings (71).

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(66) Article 11, para. 1; does this mean the competent authority may then treat the data as non-confidential?

(67) Article 11, para. 2.

(68) Article 11, para. 3.

(69) Article 6, para. 2.

(70) Article 11, para. 4.

If a Member State's legislation or administrative practices impose limits for the protection of industrial and commercial secrecy which are more strict than the Sixth Amendment's confidentiality provisions, then such Member State is not obliged to supply information to another Member State if the latter does not take steps to meet the former's more strict confidentiality provisions (72).

Public Participation

There is no provision for public participation in the Sixth Amendment.

Enforcement and Penalties

The Sixth Amendment does not direct the manner in which enforcement shall proceed in Member Sates, nor does it indicate what, if any, penalties should be applied to violations. What if a particular Member State has minimal penalties for violations? Importers into the EEC might chose that Member State for their initial notification on the grounds that enforcement and penalties are weak.

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(71) Article 11, para. 4; but what if the court proceedings are public record?

(72) Article 11, para. 4.

1.3 THE OECD CHEMICAL CONTROL PROGRAM

The Organization for Economic Co-operation and Development (OECD) consists of 24 member states with Yugoslavia as a 25th participant with special status. The OECD's members are the western industrialized democracies. The OECD is a highly respected international organization whose periodic release of comparative economic analysis rarely fails to stimulate constructive debate (and occasionally embarrassment) within each member state. Few human activities are without political overtones but is is fair to say that the OECD's activities have achieved a high level of cooperation among its members in strong distinction to some other international organizations.

The activities of the OECD in the area of chemical control are only a small part of its overall mandate. Such activities, however, are very important as trade among OECD member states accounts for most of the world chemicals trade. Total chemical sales in OECD member states in 1980 were U.S. $470 billion. In 1980 about 90% of chemicals imported into OECD countries came from other OECD member states (1).

The activities of the OECD chemical control program are oriented towards economic, environmental and trade concerns. In other words, the chemical control program seeks to address the question of how member states can acquire the economic and social benefits of chemicals while, at the same time, reduce the related negative effects on man and the environment and prevent the emergence of unnecessary and unintended barriers to trade and development (2).

A number of principles govern the work of the chemical control program. One is that chemical control should seek to anticipate and prevent harm to human health and to the environment. A second is that external pollution costs should be internalized by the responsible entity (the polluter pays principle). Third, that government and industry cooperation rather than an adversarial relationship should underpin chemical control.

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(1) From unpublished OECD documents drafted in March, 1983; obtained from Environment Canada.

(2) Ibid.

Fourth, that an international harmonized approach should be adopted for chemical control so that divergent national schemes do not arise to impede commerce and cause unnecessary use of scarce regulatory resources (3).

The work of the OECD chemical control program is done primarily by civil servants from the relevant bureaucracies in member states. Through series of meetings by sub-groups, endorsements and recommendations are made. These in themselves provide a guide for the national activities of member states. Frequently, a particular OECD member state acts as the Lead Country in coordinating a sub-group's efforts in developing a program.

Every two or three years the Environment Committee, which is the OECD entity supervising the work on chemical control, meets at what are referred to as High Level Meetings. The first such meeting was held in Paris May 19-21, 1980 and the second, also in Paris, on November 15-17, 1982. At High Level Meetings the work of sub-groups may be endorsed and particular programs or principles are then referred to the OECD Council. The latter may make a Decision or a Recommendation or Instruct that further work be done.

When a particular program or principle is made a Decision by the OECD Council it is "binding" on member states. When a member state approves a Council Decision it is committed to effecting it. However, an OECD Council Decision is different from a Directive of the EEC. The Directive known as the Sixth Amendment on chemical control must be adopted through national legislation by EEC member states. Any member not doing so may be brought before the European Court of Justice and violations are penalized. An OECD Council Decision has a political basis, not a legal basis. The failure to comply with a Council Decision does not proceed to some sort of judicial body such as the World Court (4). When the OECD Council makes a Recommendation, member states may choose whether or not to enforce it. Recommendations are not binding but they strongly influence the policy decisions of member states.

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(3) Ibid.

(4) There is another type of Council Decision embodied in a General Agreement which has more of a legal basis to it; Telephone conversation with M. Leir, Economic Law and Treaty Division, External Affairs, Ottawa, May 28, 1984.

In preparation for High Level Meetings of the Environment Committee, consultations occur with the Business and Industry Advisory Committee and the Trade Union Advisory Committee, BIAC and TUAC, so as to obtain the views of industry and labour.

Ten of the OECD's members are also members of the EEC. Twenty members (including Yugoslavia) are European countries; only Australia, Canada, New Zealand, Japan and the United States are not. This gives a distinctly European orientation to the OECD. Nine of the ten EEC members have implemented the Sixth Amendment (or their final legislation is in the last stages of enactment). It is fair to say that many of the principles and concepts considered in the OECD's work on chemical control have had a strong influence from the EEC experience.

Existing legislation concerning the notification of chemicals in OECD member states is reviewed in this report, infra. Most, if not all, member states are in the process of enacting new legislation or amending existing legislation to create or strengthen notification systems and to effect various principles and concepts which will facilitate international harmonization of chemical control.

While numerous commentaries on the work of the OECD in chemical control have been published (5), what follows is an excision from OECD documents of the major principles, programs and concepts which will have a strong influence on the development of national legislation on chemical control.

Test Guidelines

Test Guidelines were developed under the Chemicals Testing Program to provide a common basis for the acceptance of data in member states. The First High Level Meeting of the Environment Committee in May, 1980 requested that the Test Guidelines be applied provisionally in member states and that the OECD Council formally adopt the Test Guidelines.

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(5) See for example Ballew (1982), Page (1982), Gillespie (1982), Danielson (1982), Walker (1980) and to a lesser extent Dominguez (1982) and de Reeder (1980).

On May 12, 1981 the OECD Council adopted the Test Guidelines and recommended that member states, in the testing of chemicals, apply the Test Guidelines (6).

Test Guidelines Updating Program

The First High Level Meeting initiated steps for a mechanism to be established so that the Test Guidelines could be updated.

It was noted at the Second High Level Meeting in 1982 that Updating became a major activity in the extended Special Program on the Control of Chemicals in 1982.

Good Laboratory Practice

Principles of Good Laboratory Practice (GLP) were developed to provide a common basis for the acceptance of data in member states. The First High Level Meeting of the Environment Committee in 1980 requested that the GLP be applied provisionally in member states and that the OECD Council formally adopt the GLP.

On May 12, 1981 the OECD Council adopted the Principles of GLP and recommended that member states, in the testing of chemicals, apply the Principles of GLP (7).

By the Second High Level Meeting in 1982 the issues surrounding GLP had developed into the question of Mutual Recognition of Compliance with GLP; see infra.

Minimum Pre-Marketing Set of Data

Minimum Pre-Marketing Set of Data (MPD) was developed as the first element of Step

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(6) The May 12, 1981 Council Decision is reproduced in Int'l Env. Rep. 41 : 2501-4i : 2506 (1983) and Int'l Dig. of Health Leg. 32 : 533-535 (1981).

(7) Ibid.

Sequence Testing. The First High Level Meeting requested that MPD be applied in the initial assessment of new chemicals in member states and that the OECD Council formally adopt MPD as a first part of a future overall approach to Step Sequence Testing.

On December 8, 1982, the OECD Council Decision adopted the MPD (8). The Council decided that in member countries, sufficient information on the properties of new chemicals should be available before they are marketed to ensure that a meaningful assessment of hazard to man and the environment can be carried out. Chemicals subject to specific national legislation are not subject to the Decision (9). The Decision also noted that legislative or administrative procedures in a member state may provide for exemptions because of the nature of a chemical or the quantity manufactured. The Council Decision recommended that the MPD, together with its provisions for flexible application can serve (10) as a basis for a meaningful first assessment of the potential hazard of a chemical to health and the environment.

The Decision also provides that due regard may be given, on a case-by-case basis, to the scientific and economic factors that may influence the need for and the scope of testing. Member states may also omit or substitute certain tests or ask for them in a later stage of initial assessment, as long as they can justify their course of action.

Mutual Acceptance of Data

The First High Level Meeting in 1980 requested that the OECD Council formally adopt the principle of Mutual Acceptance of Data (MAD).

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(8) The Council Decision is reproduced in Int'l Env. Rep. 41 : 2601-2602 (1983) and in Int'l Leg. Mat. 22 : 909-912 (1983).

(9) For example: pharmaceuticals, pesticides, etc.

(10) Twenty-three of the 24 delegations to the Second High Level Meeting wanted this provision to read shall serve instead of can serve as the EEC already requires the MPD. The U.S. negotiated the change in wording (otherwise TSCA, which doesn't have a MPD provision would have to be amended). See: "OECD gives in to U.S. insistence on explanatory language in test set", (Current) Int'l Env. Rep. 533-534 (1982).

On May 12, 1981 the OECD Council decided that data generated in the testing of chemicals in an OECD member state in accordance with the Test Guidelines and the Principles of GLP shall be accepted in other member states for purposes of assessment and other uses relating to the protection of man and the environment (11).

Confidentiality of Data

The First High Level Meeting took steps to develop those principles and arrangements which should be followed for the transmission of data between governments while providing appropriate safeguards for commercially sensitive data and protecting their value.

Economic Aspects

The First High Level Meeting endorsed the work being done under OECD auspices on the economic and trade aspects of chemical control.

By the time the Second High Level Meeting was held in November, 1982 a number of reports had been published by the OECD on such issues (12).

Glossary of Key Technical Terms

The definitions of key terms appearing in national law and relevant international documentation and texts were collected and analyzed by an expert group under OECD auspices. Model definitions of key terms were proposed - this will help promote a convergence in terminology (13).

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(11) Ibid. Note that data acceptance is not the same thing as the acceptance of risk assessment. In effect, the commitment required by this Council Decision is to examine data from other OECD countries; not necessarily to rely on that data in risk assessment.

(12) Regulation and Innovation in the Chemical Industry (1981); Non-Tariff Barriers and the Control of Chemicals (1981); The Chemical Industry in OECD Member Countries: Statistical Characteristics (1982); The Impact of Chemical Control Upon Trade, Innovation and the Small Firm (1982); The Contribution of Economists to Decision Making [illegible] Chemicals (1982).

Step Sequence Testing

The principle of Step Sequence Testing, that new chemicals should be subject to successive levels of testing, is still under development although the MPD was recommended in the OECD Council Decision in 1981 as the first level of testing; see supra, the Council Decision adopting the MPD in 1982.

The OECD Council Decision of December 8, 1982 also instructed the Environment Committee to pursue a program of work designed to lead to the development of an overall approach to Step Sequence Testing of chemicals (14).

Existing Chemicals

Stemming from discussion at the First High Level Meeting in 1980, a Program on Existing Chemicals was developed. Work was initiated in three areas by the time the Second High Level Meeting was held in 1982.

(a) cooperation in the development nationally of internationally acceptable reviews;

(b) development of a mechanism (switchboard) for improved access to unpublished information;

(c) data gathering and assessment strategies for chemicals on the market but for which little is known of their potential health or environmental effects.

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(13) See footnote (8).

(14) The report has been published as Chemicals Control Legislation: an International Glossary of Key Terms OECD: Paris (1980).

Information Exchange

By the time the Second High Level Meeting was held in 1982, an expert group had produced a report reviewing the issues relevant to exchange of information when hazardous chemicals are exported (15).

Chemicals Group Forum

Arising from discussion at the First High Level Meeting, the Chemicals Group Forum was established for the purpose of collectively handling practical problems encountered by administrators and regulators from OECD member states.

By the Second High Level Meeting in 1982 the Chemicals Group Forum had met once to discuss the management of notification schemes for new chemicals.

At the Second High Level Meeting it was agreed that the Chemicals Group Forum should be involved in Mutual Recognition of Compliance with GLP and this was subsequently adopted by the OECD Council; see infra.

Mutual Recognition of Compliance With Good Laboratory Practice

At the Second High Level Meeting it was recognized that there was a need to ensure that the quality of test data which has been assured in one member state will be recognized in other OECD member states. A two level approach was agreed upon. National procedures should have the following common characteristics:

(a) application of the OECD Principles of GLP;

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(15) The work of the expert group was assisted by an OECD Seminar held in Yugoslavia in April of 1981; the proceedings of which were published as Control of Chemicals in Importing Countries OECD: Paris (1982).

(b) implementation of compliance procedures based on laboratory inspection and study audit;

(c) establishment or designation of a national authority to monitor compliance and discharge such other functions as may be nationally determined;

(d) certification by the test facilities that each study was carried out pursuant to provisions set by national legislation or administrative procedures dealing with GLP and was carried out in accordance with the OECD Principles of GLP.

The OECD Council adopted the above procedures in its Recommendation of July 26, 1983 (16). It recommended that member states recognize the assurance by another member state that test data have been generated in accordance with the Principles of GLP if the other member state used these compliance procedures. The Recommendation noted that member states will establish their Compliance Procedures progressively according to national priorities and it invited member states to notify the OECD as they establish them.

A second level arrangement within OECD is necessary to ensure that national procedures be mutually recognized internationally. The arrangement should have the following characteristics:

(a) the Chemicals Group Forum, discussed supra, should act as forum of representatives of national authorities responsible for GLP to discuss technical and administrative matters;

(b) that direct communication between national authorities responsible for GLP be fostered;

(c) the right of the recipient country to request information from the country of origin in the exceptional case that the recipient

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(16) The OECD Council Recommendation on this issue was reproduced in condensed version in Int'l Dig. of Health Leg. 34 : 869-870 (1983).

> country is not satisfied or able satisfactorily to verify that data are in fact in compliance with GLP (in such cases the requesting country could be invited to participate in an inspection or study audit as an observer).

The Second High Level Meeting initiated steps to establish the arrangements to give effect to these agreements concerning Mutual Recognition of Compliance with GLP.

The OECD Council Recommendation of July 26, 1983 adopted (a) and (b) above but made no mention of (c).

Proprietary Rights

The Second High Level Meeting in 1982 agreed there is a need for protection of proprietary rights to data on new chemicals submitted to administrations and requested the OECD Council to adopt the following principle:

> Each member country must require each notifier of a new chemical to identify the laboratories which produced each of the health and safety data in the notification. If the laboratories were not owned by or otherwise affiliated with the notifier, the notifier must also be required to provide certification that he had the right to use the data. If the authority receiving the notification finds that the notifier was not entitled to use the data, it must not accept the notification. This process does not change the confidentiality status of health and safety data.

This principle was adopted by the OECD Council in its Recommendation of July 26, 1983 (17).

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(17) The OECD Council Recommendation on this issue was reproduced in condensed version in Int'l Dig. of Health Leg. 34 : 870 (1983).

Transfer of Confidential Data

At the Second High Level Meeting in 1982 there was agreement on six principles related to the transmission of confidential data. Member states were invited to take steps toward creating conditions which will allow the exchange of confidential data and to explore the use of the following six principles:

(a) the exchange of confidential information on chemicals between the competent authorities of countries is intended solely to facilitate the hazard assessment of chemicals and the protection of man and the environment;

(b) a country having received information in response to a request must in no circumstances use such information for any purpose other than the assessment of hazards of chemicals and the protection of man and the environment;

(c) a country, whenever requesting information about a chemical, must substantiate the need for the information, on the grounds that:

  (i) the chemical is present or is shortly to be marketed in its territory; and

  (ii) the information is necessary for the assessment of its hazards and the protection of man and the environment.

(d) a country requesting information:

  (i) must abide by the decision made by the transmitting country in respect to the confidential nature of the information;

  (ii) must treat the transmitted information with at least the same degree of confidentiality as is practised in the country from which the information has been requested;

(iii) may make the information available to national, regional or local authorities only when necessary for purposes of hazard assessment of chemicals or protection of man and the environment and only when such authorities are able to guarantee the same level of confidential treatment;

(iv) shall not transmit the information received to any other country.

(e) the requesting country shall not ask for the transmission of confidential information which it does not have the authority to collect and use under its legislation or in the normal course of its administration;

(f) the solicited country should consult with the person who submitted the requested confidential data before transmitting them.

The OECD Council, in its Recommendation of July 26, 1983 (18), recommended that member states take steps towards creating conditions which will allow the exchange of confidential data and invited member states to explore the use of the above six principles.

Non-Confidential Data

The Second High Level Meeting in 1982 endorsed the OECD List of Non-Confidential Data and requested the OECD Council to adopt it. It also invited member states to facilitate the exchange of listed data and other data which, under national circumstances, may be deemed to be non-confidential for purposes of assessment and other uses relating to the protection of man and the environment. The List of Non-Confidential Data is as follows:

(a) trade name(s) or name(s) commonly used (in the U.S. these may mean a generic name of a chemical substance);

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(18) The OECD Council Recommendation on this issue was reproduced in condensed version in Int'l Dig. of Health Leg. 34 : 870-871 (1983).

(b) general data on uses (the uses need to be described only broadly, like: closed or open system, agriculture, domestic use, etc.);

(c) safe handling precautions to be observed in the manufacture, storage, transport and use of the chemicals;

(d) recommended methods for disposal and elimination;

(e) safety measures in case of an accident;

(f) physical and chemical data with the exception of data revealing the chemical identity (e.g. spectra); if the physical and chemical data make it possible to deduce therefrom the chemical identity, only ranges of values need be given;

(g) summaries of health and safety data including precise figures and interpretations (the submitter of the health and safety data should participate in the preparation of the summaries).

The OECD Council Recommendation of July 26, 1983 (19) adopted the invitation set out above and the List of Non-Confidential Data. The List was accompanied in the Recommendation by the following:

> ... "non-confidential" means that no restrictions should be put on the exchange of the data between governments nor on the disclosure of such data to the public. Proprietary rights to data are not affected by the non-confidential status of such data. Data should be exchanged between governments on request and not as a matter of routine.
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> The (List of Non-Confidential Data on Chemicals) is not restrictive. It is recognized, on the contrary, that in some circumstances there

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(19) The OECD Council Recommendation on this issue was reproduced in condensed version in Int'l Dig. of Health Leg. 34 : 871-872 (1983).

may be other data which are considered non-confidential both by government and the submitter and that if these are useful for hazard assessment of chemicals, they should also be exchanged. The (List) is inspired by the OECD MPD, but is not meant to be restricted to information on new chemicals. Non-confidentiality, as defined above, applies to all chemicals.

Data Interpretation Guides

The Guidelines for Testing of Chemicals, discussed supra, provide a common basis for developing test data, but test data must then be interpreted and an integrated assessment made. In order that a new hazard assessment will not necessarily have to be made every time a chemical enters an additional market, Data Interpretation Guides (DIG) have been developed, covering 21 test parameters (20).

The Second High Level Meeting requested that the DIGs be used after their review in member states in order to gain experience prior to further action.

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(20) Additionally, guidance on preferred information regarding production/use/disposal data for exposure analysis has been prepared.

2.1 BELGIUM

Belgium is a constitutional monarchy. The written Constitution establishes a separation between legislative, executive and judicial powers. As well, the Constitution recognizes three Communities (Flemish, French and German) and three Regions (Flemish, Walloon and Brussels). Communities and Regions are governed by various local Councils with legislative and executive powers. Further, the country is divided into nine Provinces and 596 Communes.

The national legislative authority is the King acting jointly with a two chamber Parliament. Most powers concerning environmental matters are in the hands of the national government. The Regional administrations have a certain independence in economic affairs although they are often limited to application of national legislation.

Over the last 15 years Belgium has consciously evolved to a more decentralized government system, largely in an effort to quell cultural antagonism between French and Flemish citizens. While Belgium has recently developed a comprehensive body of environmental law, it is not subject to any coherent framework or unified by any global objective, nor has local administration been adequately and equally effected throughout the country (1).

There is a Ministry of the Environment which has been described as "skeletal", set up merely to coordinate legislation and its application (2).

During 1982, however, a large number of pieces of environmental legislation were introduced by the national government (3). One of them, Royal Decree No. 82-1000 of May

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(1) McLoughlin and Forster (1982); (Reference) Int'l Env. Rep. 22 : 0101 (1981); Price Waterhouse, Doing Business in Belgium (1983).

(2) (Reference) Int'l Env. Rep. 22 : 0101 (1981).

(3) "Belgium: Belgians Take Steps to Align Laws With EEC Environmental Directives", (Current) Int'l Env. Rep. 5 : 546 (1982).

24, 1982, implemented the EEC's Sixth Amendment on the marketing of chemical substances (4).

Overview

Belgium's legislation implementing the EEC Sixth Amendment is a comprehensive Royal Decree. It has eight Annexes appended to it. Annexes VII and VIII are virtually identical to Annexes VII and VIII of the Sixth Amendment. The main body of the Royal Decree follows closely the Sixth Amendment.

There were two Royal Decrees published in 1981 which partially implemented the Sixth Amendment. These dealt with the classification, packaging and labelling of dangerous substances and preparations for marketing or utilization (5).

Status of Implementation

Royal Decree No. 82-1000 was enacted on May 24, 1982 and came into force on July 2, 1982 (6). As of that date new substances must be notified to the Belgium competent authority.

Purpose or Scope of the Legislation

The Royal Decree was enacted so as to regulate the marketing of substances which might be dangerous to man or the environment. The preamble to the Decree makes reference to the health and safety of workers. Yet the Royal Decree taken as a whole is no more comprehensive than necessary to implement the Sixth Amendment.

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(4) Royal Decree No. 82-1000 To Regulate the Marketing of Substances Which Might be Dangerous for Man or his Environment, Moniteur Belge, July 2, 1982, p. 789.

(5) English copies of these two Decrees are not readily available. Royal Decree of March 19, 1981, Moniteur Belge, March 26, 1981, pp. 3649-3650, was noted in IRPTC Bull. 4 : 28 (1981) and Ecochem Bull. No. 183 (May 1981). The early Royal Decree was that of April 9, 1980.

(6) Article 12 - Royal Decree No. 82-1000.

Effective Date of Notification Requirement

As of July 2, 1982 new substances marketed in Belgium must be notified to the competent authority.

Type of Notification

Notification is required before "marketing" a substance (7). "Marketing" means "to bring to the marketplace" and more specifically: "Delivery and putting at the disposition of a third party, as well as importation" (8). Therefore, the Belgium notification system is one of pre-marketing and pre-importing.

Notification Time Period

The marketing of a substance may not occur until at least 45 days after receipt by the competent authority of the notification material (9).

Responsibility for Notification

Manufacturers and importers of new substances are responsible for notification (10). Neither "manufacturer" or "importer" is a defined term. These are important terms. Will difficulties arise in the administration of the notification system because of a lack of precision in the identification of the major players?

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(7) Article 2, para. 1.

(8) Article 1, para. 1, item (c).

(9) Article 3.

(10) Article 2, para. 1.

Notification Authority

Notification material must be sent by registered mail to the "Minister or Secretary of State who is responsible for Public Health" (11). The Commission of Dangerous Products is the office to which material for the Minister is to be addressed (12). The Commission is under the Ministry of Public Health and is composed of civil servants from four government ministries (13). The Commission is responsible for evaluating the submitted material (14) and it must report back to the Minister within 40 days of receipt of the notification material (15). The Commission may take the advice of non-voting consultants appointed by the Minister (16) and may also seek the opinion of the Superior Council of Public Hygiene (17).

Chemicals to be Notified

The Royal Decree does not apply to (18):

- food products;
- animal feed;
- medicine and narcotics;

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(11) Article 2, para. 1; Article 1, para. 1, item (d); Article 4.

(12) Article 4.

(13) Article 5, para. 1.

(14) Article 5, para. 3.

(15) Article 5, para. 5.

(16) Article 5, para. 1.

(17) Article 5, para. 4.

(18) Article 1, para. 4.

- phytopharmaceutical articles (19);
- waste material;
- substances in transit under the control of customs, unless they will be subject to treatment or transformation;
- transport of dangerous substances;
- radioactive substances.

The Royal Decree does not apply to substances exclusively destined to be utilized as food products, animal feed, medicine, narcotics or phytopharmaceutical articles. In theory, if a substance in those categories has other uses, the substance would fall within the jurisdiction of the Decree.

"Substances" in either their original state or as used in preparations must be notified to the competent authority before marketing (20). "Substances" are defined as "chemical elements and their components in their natural state or as they are produced by industry or by human activity, possibly containing any auxiliary substances necessary for their marketing" (21). "Preparations" are defined as "mixtures or solutions consisting of two or more substances" (22).

The Royal Decree does not mention "new substances". However, the notification system does not apply to substances listed in the EEC inventory of substances on the market in the EEC as of September 18, 1981 (23). In this sense the notification system applies only to substances new to the market since September 18, 1981.

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(19) The term "phytopharmaceutical" is not defined. One can think of many possible and radically different meanings. Perhaps the term suffers from poor translation.

(20) Article 2, para. 1.

(21) Article 1, para. 1, item (a).

(22) Article 1, para. 1, item (b).

(23) Article 1, para. 5, item (b).

Total Exemptions

Notification is not required of the following:

(a) EEC exemption - The Royal Decree does not clearly set forth an EEC exemption. Instead, the definition of "marketing" states that if substances and preparations are imported from an EEC Member State they are "considered to be already suitable for marketing since they already have undergone a disclosure procedure at least equal to the one described in this present Decree" (24). This statement implies that notification is not required (25).

(b) Polymer exemption - if the substance is a polymer, polycondensate or polyaddition composed of at least 2% by weight of a bound monomer, which has not been commercialized before September 18, 1981 (26).

(c) Testing exemption - if the substance is in the process of research and analysis and is marketed in order to determine its characteristics in accordance with the Decree (27).

(d) Research exemption - if the substance is put on the market for the purpose of research or analysis in quantities less than one tonne per year, and intended only for use in laboratories (28).

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(24) Article 1, para. 1, item (c).

(25) The drafters of the Belgian legislation must have been very trusting souls. Did they contemplate that one Member State, Greece, would not implement the Sixth Amendment (at least to date)? As it stands now, a Canadian firm could bring a new substance into Greece and then export it to Belgium without having to notify either Greece or Belgium. The other EEC Member States have carefully stated that notification will not be required if the substance has been notified elsewhere in the EEC in accordance with the Sixth Amendment.

(26) Article 9, para. 1, item (a).

(27) Article 9, para. 1, item (b).

(28) Article 9, para. 1, item (c).

Partial Exemptions

(a) Quantity exemption - if the substance is put on the market in a quantity less than one tonne per year per manufacturer (29).

However, in this case, the manufacturer must submit to the competent authority the identity of the substance, its characteristics as required for labelling and the quantity put on the market. There is also a condition that the manufacturer conform to the Minister's eventual directive.

(b) Ten year exemption - if the substance has previously been notified to the competent authority, at least ten years in the past, then the technical dossier otherwise required to be submitted on notification is reduced to a minimal level (30).

(c) Partial research exemption - if a substance is put on the market for the purpose of research and development and if the quantity is greater than one tonne per manufacturer or importer, then notification is not required for a period of one year (31).

In this case, marketing must be limited to quantities necessary for research and development and the substance must be furnished only to a "limited number of registered clients" (32). The manufacturer or importer must submit the following to the competent authority:

(i) the identity of the substance;
(ii) the characteristics used for labelling;

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(29) Article 9, para. 1, item (d).

(30) Article 2, para. 3. The identity, use and production information must be submitted. The physico-chemical, toxicity and ecotoxicity tests need not be submitted.

(31) Article 9, para. 2.

(32) Does "registered client" mean that the name of the recipient must be submitted to the competent authority?

(iii) the quantity supplied;

(iv) an assurance that an eventual directive will be complied with;

(v) an assurance that the substance will not be available to the public (33);

(vi) if the substance is "toxic" or "very toxic", information regarding handling precautions, and first aid and emergency measures (34).

Inventory

The Royal Decree relies on the EEC inventory of substances on the market in the EEC before September 18, 1981 in order to distinguish between "new" substances requiring notification and "old" substances which don't (35).

There apparently is a Belgian inventory of dangerous substances referred to in Annex I of the Royal Decree. This list is the same as that in the Belgian General Regulation for the Protection of Labour (36). If a substance is already on this list then some information, otherwise required to be notified, may be dispensed with.

Content of Notification

The notification system requires that a "disclosure dossier" be submitted to the competent authority. This contains the following (37):

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(33) In other words, "to put on the market" for this partial exemption means to supply to a client for research and development purposes.

(34) Article 9, para. 4.

(35) Article 1, para. 5.

(36) Royal Decree of May 29, 1978, Moniteur Belge, June 23, 1978 as amended by Royal Decree of February 13, 1981, Moniteur Belge, March 4, 1981.

(37) Article 4, para. 1.

(a) technical dossier - furnishing "all the information" the notifier "might reasonably possess", permitting the appraisal of foreseeable risks, whether immediate or deferred, which the substance may present to man or the environment. Specifically:

  (i) the information and study results covered in Annex VII (which is the same as Annex VII to the Sixth Amendment);

  (ii) complete descriptions of the studies and the methods used or

  (iii) bibliographic references.

(b) declaration - concerning unfavourable effects of the substance based on various foreseen uses.

(c) proposed classification and labelling (38).

(d) proposed recommendations concerning the safe use of the substance.

(e) a resume or abstract of the disclosure dossier.

Testing Requirements

As mentioned above, the notification material must contain the results of the tests and studies outlined in Annex VII of the Sixth Amendment; the "base set" of tests. Further tests may be required depending on the quantity of substance put on the market, as discussed, infra.

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(38) As per the Decrees noted in footnote (5).

Mutual Acceptance of Data

As mentioned in the section supra regarding "Exemptions", notification is (impliedly) not required for substances of which notification has been given to the competent authority in another Member State of the EEC.

One of the functions of the Commission for Dangerous Products is to examine the dossiers which the Commission of the European Communities transmits to the competent authority (39). The competent authority is responsible for transmitting the resume, supplied by the notifier, to the CEC (40). The Royal Decree contains implied provisions regarding the possibility of transmitting information to other Member States of the EEC.

Flexibility in Notification Requirements

Other than the exemptions noted above there does not appear to be provision for the omission or substitution of the basic information to be supplied.

There are, however, further tests required if the quantity of substance put onto the market reaches certain levels (41). The further testing requirements are as follows:

(a) 10 tonnes/50 tonnes - if the quantity put on the market reaches 10 tonnes per year or 50 tonnes cummulative the results of Level One tests of Annex VIII may be required to be submitted.

(b) 1000 tonnes/5000 tonnes - similarly, results of further tests as set out in Level Two of Annex VIII will be required to be submitted, but only under a specific study program designed by the government.

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(39) Article 5, para. 3, item (c).

(40) Article 6.

(41) Article 7.

Notably, there is no mention of the 100/500 tonne levels. As set out in the Sixth Amendment, there is a certain amount of discretion involved in these testing requirements, but the Sixth Amendment requires that the Annex VIII Level One tests be done if the 100/500 tonne levels are reached.

As mentioned supra in the section on "Inventory", Annex I to the Royal Decree refers to an existing list of dangerous substances which has been prepared pursuant to the country's occupational health and safety legislation. If a substance is already on that list, a notifier may omit the following information in its submission (42).

(a) the declaration concerning unfavourable effects;
(b) the proposed classification;
(c) the proposed recommendation concerning safe usage.

Further Testing/Follow-up Measures

As mentioned, further testing may be required if the quantity of substance placed on the market reaches certain levels.

Once a substance has been notified, the notifier is under an obligation to provide further information to the competent authority as follows (43):

(a) changes in quantities per year, or accumulated quantities, placed on the market at the following levels: 1, 10, 50, 100, 500, 1000 and 5000 tonnes;

(b) new knowledge relating to the effects of the substance upon man and/or the environment, of which the notifier may reasonably have knowledge of;

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(42) Article 2, para. 3.

(43) Article 7.

(c) new uses for which the substance is put on the market;

(d) all modifications of characteristics which result in the modification of the substance's composition.

The Commission of Dangerous Products is authorized to analyze samples of substances and to request additional informational and/or verification studies with respect to notified substances (44).

Special Orders

There is no express provision in the Royal Decree authorizing the competent authority to impose special conditions on the marketing of new substances. This is, of course, aside from the usual complementary legislation regarding labelling and handling of chemicals.

Protection of Confidential Data

The Royal Decree provides that every person participating "or called upon to participate in the work of the Commission" (45) is required to observe strict discretion concerning any information or documentation of which he may acquire knowledge in the course of the work (46).

A notifier may request that information to be supplied upon notification, upon additional testing or the information concerning on-going changes in quantities, use, etc. be kept secret. The claim for secrecy may be made against all persons other than those involved in the Belgian notification system, the CEC and the competent authorities of the EEC Member States. The request must be justified (47).

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(44) Article 5, para. 4.

(45) Presumably this is to cover the outside expert consultants who, from time to time, may advise the Commission of Dangerous Products.

(46) Article 5, para. 6.

(47) Article 8, para. 1.

The competent authority will only transmit "secret information" to other EEC Member States if there are similar strict safekeeping requirements in place. Before disclosure the notifier must be consulted (48).

Some information can not be kept secret (49):

(a) commercial name of the substance;
(b) physico-chemical characteristics;
(c) methods of making the substance harmless;
(d) interpretation of toxicological and ecotoxicological studies;
(e) name of the person doing the above studies;
(f) recommended precautions for handling and emergency measures, etc.

Once a claim has been made for confidentiality the permission of the competent authority is required before the notifier can make the information public (50).

A substance may be placed on a list of disclosed substances by code name, for a limit of three years, if approved by the competent authority and as long as the substance has not been classified as "dangerous" (51).

Disclosure of Data and Proprietary Rights

As mentioned, there is impliedly a list of disclosed substances which may be published (52), but further details are not provided. Also, some information outlined above can not be kept secret. But there is no express mechanism for general disclosure of data, other than to the CEC and Member States of the EEC.

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(48) Ibid.

(49) Ibid.

(50) No reason for this peculiar provision in Article 8 is apparent. The Sixth Amendment has a similar provision but does not refer to "permission".

(51) Article 8, para. 2.

(52) Ibid.

There is provision in the Royal Decree for a subsequent notifier to use the results of studies done by previous notifiers for a previously notified substance (53). There is no express provision for proprietary rights. If a claim for confidentiality has been previously made, presumably a subsequent notifier would have to directly approach the initial notifier for the specific details. There is no indication that the competent authority is required to approve commercial arrangements for the sharing of data between notifiers.

Public Participation

There is no provision in the Royal Decree for participation by the public in the decision-making process.

Enforcement and Penalties

The Royal Decree is incomplete on this issue. One provision suggests that a further Decree will be promulgated (54). However, it is stated that "infractions against the provisions" of the Decree (it does not say which provisions) will be punished in accordance with penalties established in a Law of February 24, 1921 concerning the traffic in venomous, soporific, narcotic, disinfecting and antiseptic substances (55). One can not help thinking that fines established in a 1921 Law would not be particularly severe (unless amendments to the penalty provisions have been made over the last sixty years).

Interestingly enough, there is a provision that documented infractions will be considered valid until proven invalid (56). This "reverse onus" clause is unusual.

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(53) Ibid.

(54) Article 10, para. 1.

(55) Article 11.

(56) Article 10, para. 2.

2.2 DENMARK

Denmark is a centralized constitutional democracy. The government has three levels: municipalities, counties and the unicameral national Parliament (The Folketing). The Folketing has supreme legislative power under the Constitution. Municipalities administer many laws. The importance of the county councils has declined (1).

The Ministry for the Environment and its "directorate", the National Agency of Environmental Protection, were both established in 1973. The Environmental Appeal Board hears appeals from the more important decisions made in environmental matters (2).

Denmark has complied with the EEC Sixth Amendment. The Chemical Substances and Products Act (3) was enacted in 1979. It is administered by the National Agency of Environmental Protection, a part of the Ministry of the Environment. Two complementary Statutory Orders have been issued under the Act. One of them (4) is concerned with the classification, packaging, labelling and storage of dangerous chemical substances and products. This Order is administered by the State Chemical Supervision Service and the Municipal Councils.

The other Order is Statutory Order On Notification of Chemical Substances (5). The Danish government has published a guide booklet to the Order (6).

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(1) McLoughlin and Forster (1982).

(2) (Reference) Int'l Env. Rep. 221 : 0101 (1978).

(3) Act No. 212 of May 23, 1979, published in (Reference) Int'l Env. Rep. 221 : 4501-4506 (1980). This Act was amended by Act No. 68 of February 20, 1980.

(4) Statutory Order No. 408 of September 17, 1980, published in (Reference) Int'l Env. Rep. 221 : 4521 (1981).

(5) Statutory Order No. 409 of September 17, 1980, published in (Reference) Int'l Env. Rep. 221 : 4581-4585 (1981).

(6) Registration of Chemicals, Ministry of the Environment.

It should be mentioned that Denmark has a parallel notification system in operation concerning substances used in connection with work carried out for commercial purposes. The Order On Substances and Materials (7) requires persons intending to manufacture or import commercially for the first time a substance or material which may endanger or otherwise impair safety or health to notify the Directorate of Labour Inspection. From the available material it appears that this notification system is very similar to the notification system to be discussed infra. The Order was issued pursuant to a law on occupational health and safety (8). It is not clear whether, or how, this notification system is integrated or coordinated with the notification system established pursuant to the Sixth Amendment. There is some indication that integration is not contemplated. The Chemical Substances and Products Act states (9):

> The provisions applying to chemical substances and products in other legislative texts shall not be affected by this Act which shall only apply to chemical substances and products in so far as provisions thereon are not laid down in other legislative texts.
>
> The provisions of Part 3 (notification provisions) shall apply irrespective of rules on notification of chemical substances laid down in other legislative texts ...

Overview

The Danish legislation is more comprehensive or "tough" than the Sixth Amendment. A substance must be notified if it is new to the Danish market, not just new to the EEC market. In other words, a substance might be on the EINECS inventory, but if it is new to Denmark, it must be notified to the Danish competent authority. This certainly defeats one of the purposes of the Sixth Amendment which is to harmonize the laws of Member States so that commerce is not impeded by different national requirements. As it stands, an importer would have the responsibility of checking two inventories, instead of one, to see if notification is necessary. The legislation is also more "tough" than the Sixth Amendment in that existing chemicals (sold in or imported into Denmark before October 1, 1980) must be notified in the same way as "new" chemicals if they are sold or imported for "significantly altered purposes or in significantly increased quantities". Less importantly, for our purposes, the classification of dangerous substances in Denmark includes a few chemicals in addition to those in the EEC classification (10).

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(7) Order No. 540 of September 2, 1982 On Substances and Materials, Lovtidende for Kongeriget Danmark, 1982, Part A, October 16, 1982, No. 81, pp. 1559-1574, published in condensed form in Int'l Dig. of Health Leg. 34 : 124-126 (1983).

(8) Law No. 681 of December 23, 1975 On the Occupational Environment. See Int'l Dig. of Health Leg. 28 : 39 (1977).

(9) Section 7 - Act.

The Danish competent authority appears to have greater discretion than those of other countries. For example, further testing requirements (eg. the Annex VIII tests) are not precisely set out in the legislation but power is given to the competent authority to request further tests. The competent authority also has express power to "derogate" from the notification requirements in "special cases".

Also in distinction to most other countries, the Danish legislation has express provisions relating to exports, biotechnology and public participation. The legislation appears to be lacking in respect to confidentiality provisions for the transmittal of data to other EEC Member States.

Status of Implementation

As noted, Denmark has implemented the Sixth Amendment notification system with the enactment of the Chemical Substances and Products Act and the issuance of Statutory Order No. 409 On Notification of Chemical Substances.

Purpose or Scope of the Legislation

The Act states that its objective is to prevent damage to health and the environment caused by chemical substances and products (11). Unlike many other implementing laws in the EEC, the Danish Act states that the measures taken to prevent damage shall balance the potential damage with the technical and economic consequences, including costs, of such measures (12).

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(10) Springborn (1982).

(11) Section 1 - Act.

Effective Date of Notification Requirement

The Act came into force on October 1, 1980 (13). Order No. 409 of September 17, 1980 also came into effect on that date (14).

Type of Notification

Producers or importers "planning to sell or import" a new chemical substance must notify the competent authority (15). The system is therefore a pre-marketing and pre-import notification scheme.

Notification Time Period

The original version of the Act stated that a new chemical substance could not be sold or imported until one month after receipt of notification (16), unless the information supplied was insufficient - in which case one month after receipt of a complete notification (17).

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(12) Section 3 - Act. This policy statement in the Act would suggest that the law will be administered with a significant degree of administrative discretion. One notices the similarity between this policy statement and that contained in the American TSCA.

(13) Section 65 - Act.

(14) Section 23 - Order.

(15) Section 12 - Act; Section 12 - Order.

(16) Subsection 12(3) - Act.

(17) Subsection 14(2) - Act.

The Act was amended (18) and presumably the time period in the Act was extended to 45 days because Order No. 409 provides that a notified chemical substance and products of which it forms part, shall not be sold or imported until 45 days after receipt of the completed notification (19).

Responsibility for Notification

"Producers" and "importers" are responsible for notification of new chemical substances to the competent authority (20). The Order refers to "manufacturer" instead of "producer". None of these three terms is defined in either the Act or the Order (21).

Notification Authority

The Order provides that notification material must be sent, in duplicate, to the National Agency of Environmental Protection (NAEP). There is a special notification form prepared by the NAEP (22). Both the NAEP and the State Chemical Supervision Service are charged with the supervision and control of the provisions of Order No. 409 (23) but specific duties are laid out for the NAEP and not for the State Chemical Supervision Service.

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(18) Act No. 68 of February 20, 1980. An English copy of this Act is not readily available. However, Order No. 409 was issued subsequent to Act No. 68 and we may safely assume that the amendments are reflected in Order No. 409.

(19) Section 12(1) - Order.

(20) Section 12(1) - Act.

(21) Section 3(2) - Order. As mentioned several times in this review, the lack of a precise definition of "importer" may cause problems as there are frequently several legal entities involved in an import transaction.

(22) Section 4 and Subsection 12(1) - Order. The notification form appears as an Annex to Order No. 409.

(23) Section 17 - Order.

Chemicals to be Notified

"Chemical substances" are chemical elements and their compounds, as they occur in their natural state or as produced by industry (24). "Chemical products" are solutions as well as solid, liquid or gaseous mixtures composed of two or more chemical substances (25).

Notification is required for "new chemical substances" which are defined as chemical substances which have not been sold in or imported into Denmark before October 1, 1980 either as a chemical substance or as a component of a chemical product. Pre-October, 1980 substances must also be notified if they are sold or imported after October 1, 1980 for "significantly altered purposes or in significantly increased quantities" (26).

The legislation does not apply to (27):

- chemical waste;
- substances in medicinal products;
- additives to foodstuffs;
- additives to animal feedingstuffs;
- substances transported through Denmark as "transit goods" (28).

Significantly, in distinction to most other countries, the Danish legislation expressly applies to the export of new chemical substances if they have been produced in Denmark (29).

The Act anticipates the regulation of biotechnology products. The Minister for the Environment may decide that products, the properties of which depend upon the content of vira, bacteria, fungi or other microorganisms, shall be covered by the provisions of the Act in full or in part (30). There is no indication that the Minister has made such a decision. Chemicals produced through the use of biological organisms would require notification in most countries with notification schemes, but the provision that products which themselves contain biological organisms may be subject to notification is unusual. As biotechnology develops we may expect to see more biological products, such as microorganism cultures, marketed and imported as the "raw materials" for the industrial production of chemicals. Denmark will not have to amend its Act to control them. However, biohazards have properties and characteristics radically different from chemical hazards. New and more appropriate tests would have to be devised for any notification scheme expected to cover biohazards.

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(24) Subsection 3(1) - Act.

(25) Subsection 3(2) - Act.

(26) Section 2 - Order; Section 11-Act.

(27) Subsection 7(2) - Act. Unless otherwise decided by the Minister.

(28) Subsection 8(2) - Act.

(29) Subsection 8(1) - Act.

Total Exemptions

(a) Resale exemption - if a notified substance is resold and then used in the production of a chemical product, notification is not required (31).

(b) Research exemption - if a substance is sold or imported in a quantity less than one tonne/year/manufacturer or importer and the substance is intended for laboratory research and analysis purposes (32).

(c) EEC exemption - if a new chemical substance is imported into Denmark from another Member State, then notification is not required provided the substance has been notified to that Member State in accordance with the Sixth Amendment. However, the importer in Denmark must inform the competent authority of the impending import and must provide a declaration that the substance has been duly notified elsewhere - but no other information is required (33). But note that "new chemical substance" retains its definition as a substance not marketed in or imported into Denmark before October 1, 1980. Hence, an importer must check the Danish inventory to determine if notification is necessary.

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(30) Subsection 5(1) - Act.

(31) Subsection 3(2) - Order; Subsection 12(2) - Act.

(32) Subsection 6(1) and Subsection 8(2) - Order. Although if it is possible, the substance must be classified and labelled in accordance with Order No. 408 - but this information is not submitted.

(33) Section 9 - Order.

(d) Polymer exemption - if the substance is a polymer containing in combined form less than 2% of a new monomer (34). In this case, however, the substance must be classified and labelled in accordance with Order No. 408 and if it is "very toxic" or "toxic", the notifier must submit proposals regarding precautionary and emergency measures (35).

Partial Exemptions

(a) Quantity exemption - if the quantity sold or imported is less than one tonne/year/manufacturer or importer then the notifier must submit information on the identity of the substance, the quantities sold or imported and the data on the basis of which the substance is labelled (36). If "very toxic" or "toxic", the notifier must submit proposals regarding precautionary and emergency measures (37).

(b) Partial research exemption - if the substance is at the stage of research and development and is sold or imported for the purpose of industrial research and development within "a limit number of undertakings" (38), the notifier must submit information on the identity of the substance, the quantities sold or imported and the data on the basis of which the substance is labelled (39). As well, the notifier must indicate the undertakings to which the substance is sold. This exemption expires one year from the date of sale or importation (40).

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(34) Subsection 6(2) - Order.

(35) Subsections 7(1) and 8(1) - Order.

(36) Subsections 6(1) and Subsection 8(2) - Order.

(37) Subsection 8(1) - Order.

(38) Subsection 6(3) - Order.

(39) Subsections 8(2) and 8(3) - Order.

(c) Ten year exemption - if the substance was originally notified at least 10 years previously, a notifier need submit only the following (41):

- (i) identity of the notifier;
- (ii) identity of the substance;
- (iii) information on the substance in the commercial form;
- (iv) information relating to the determination of the substance;
- (v) information on the manufacture, use, quantity and distribution of the substance;
- (vi) proposals regarding precautionary and emergency measures.

Inventory

The Danish legislation makes no mention of the EEC inventory. Denmark has its own inventory of substances sold in or imported into Denmark before October 1, 1980. That inventory is not expressly mentioned either but is implied in the definition of "new" chemical substance.

Content of Notification

Notification of a new chemical substance requires the submission of information set out in the Annex to Order No. 409, which is substantially the same as Annex VII of the Sixth

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(40) Subsection 8(3) - Order.

(41) Subsection 15(4) - Order.

Amendment (42). Unlike the laws of the other EEC Member States, the Danish scheme does not refer to a "technical dossier", "declaration" or "summary".

Testing Requirements

The tests set out in Annex VII of the Sixth Amendment, the "base set" of tests, are substantially the same as the tests set out in the Annex to Order No. 409.

Mutual Acceptance of Data

As mentioned supra, if a substance has been notified in accordance with the Sixth Amendment elsewhere in the EEC by a manufacturer or importer, that notifier may then import the substance into Denmark without submitting the notification material - although a declaration that the substance has been duly notified must be submitted (43).

Flexibility in Notification Requirements

Order No. 409 expressly provides that one or more of the particulars required in the notification may be omitted for "technical or professional reasons", but such reasons must be explained in the notification (44).

The Annex to Order No. 409 does not contain the tests described in Annex VIII of the Sixth Amendment. The Order does not specify when tests in Annex VIII will be required - there is no mention of the specified levels (10/50, 100/500, 1000/5000 tonnes) which may trigger the Annex VIII tests. The possibility of such changes in notification material are dealt with in broadly worded provisions discussed infra.

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(42) Section 5 - Order.

(43) Section 9 - Order.

(44) Subsection 5(3) - Order.

The Danish legislation has an express provision for discretion on the part of the competent authority. In "special cases" the competent authority may provide for "derogations" from the notification rules (45).

Further Testing Requirements/Follow-up Measures

Denmark has dealt with notification requirements for "changed circumstances" in a manner different from other countries. If a substance has been sold in or imported into Denmark before October 1, 1980 it is not considered "new" and does not require notification except if (46):

(a) it is sold or imported for "significantly altered purposes"; or

(b) it is sold or imported in "significantly increased quantities".

In which case the substance must be notified to the competent authority and the notification material required is the same as if the substance were a "new chemical substance" ie: the information and tests set out in the Annex (47). The same exemptions (quantity, polymer, testing) which apply for "new chemical substances" also apply to the "old" substance (48). The legislation does not say what is "significant". Are the "significantly increased quantities" the 10/50, 100/500 and 1000/5000 tonne levels referred to in Annex VIII of the Sixth Amendment? It is not stated in the legislation. Even so, the Annex to Order No. 409 doesn't outline the Annex VIII Sixth Amendment tests which should be applied when substances reach those specified levels.

There are further testing requirements. Regardless of whether a substance is "new" or "old" (as discussed above), once a substance is notified to the competent authority the notifier must inform the competent authority of "significant alterations in or additions to previously filed information" (49). At the request of the competent authority, a notifier "shall carry out or have carried out tests in addition to those specified in the Annex". A specified time period may be given for completion of the tests (50). The competent authority may also request samples (51).

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(45) Section 18 - Order.

(46) Subsection 2(2) - Order.

(47) Section 10 - Order.

(48) Section 11 - Order.

The Order provides that the competent authority may lay down rules on recommended or obligatory test methods (52). This could refer to the Annex VIII tests of the Sixth Amendment.

Special Orders

As mentioned, the competent authority has discretion powers as well as the specific power to require further tests. To what extent these are used is not known.

The Minister of the Environment has broad powers under the Act to restrict or ban the sale, import or use of any substance which may present a hazard (53).

The Act also provides that the competent authority "may issue orders or prohibitions in case of violation" of the Act or Order (54). This is a very broad power. There is provision for complaints to be made to the Environmental Appeal Board concerning decisions made by the competent authority under this power (55).

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(49) Subsection 13(1) - Order.

(50) Subsection 14(1) - Order.

(51) Subsection 14(2) - Order.

(52) Subsection 16(1) - Order.

(53) Section 30 - Act.

(54) Section 48 - Act.

(55) Sections 19 and 20 - Order.

Protection of Confidential Data

Persons exercising authority under the notification system are subject to the provisions on professional secrecy of the Danish Civil Penal Code (56). The notification form provides that the notifier may request that some information be kept confidential, but "full justification" must be given (57). An express list of non-confidential data is not given, unlike the notification systems of many other countries. There does not appear to be express provisions for confidentiality protection in the transmittal of data to other EEC Member States.

Disclosure of Data and Proprietary Rights

A notifier may refer to the information filed by a previous notifier with respect to the same substance if the latter agrees and proof of that agreement is provided. Some of the basic information such as identity and composition of the substance must be given in any event (58).

Public Participation

The Danish legislation is unusual in that it provides that before the Minister lays down rules under the Act, he must "negotiate" with the relevant national trade and consumer organizations, including labour and management, and associations of local authorities (59).

It is not clear whether a member of the public may make a complaint to the Environmental Appeal Board.

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(56) Section 58 - Act.

(57) Section 18 - Annex to Order.

(58) Subsection 15(2) - Order.

(59) Section 9 - Act.

Enforcement and Penalties

The Minister has ample power to delegate enforcement powers to local councils (60). The competent authority has certain search and seizure powers (61).

Violation of the notification provisions may result in a fine or imprisonment up to one year (62). A maximum fine is not given.

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(60) Section 46 - Act.

(61) Sections 49 and 50 - Act.

(62) Section 22 - Order.

2.3 FRANCE

The French Constitution of the Fifth Republic combines the characteristics of parliamentary and presidential regimes. There is ministerial responsibility to a two chamber Parliament, the principal legislative authority. The President has power to legislate in times of crisis.

Other than laws enacted by Parliament, the government can issue decrees on certain matters, both autonomously and under powers granted by legislation. Ministers and even local authorities may be granted powers to issue decrees.

The Ministry of the Environment has general responsibility for protecting the environment and improving the quality of life. There are several Interministerial organizations such as The Interministerial Committee on the Quality of Life and The High Committee for the Environment which help develop policy (1).

Overview

The Chemicals Control Law (Law No. 77-771 of July 12, 1977) came into effect on July 12, 1977 (2). Many of its provisions echo the Sixth Amendment even though it predates the Sixth Amendment. This may be because the primary political and professional force behind the passage of the Sixth Amendment in 1979 was French (perhaps the Sixth Amendment echos the Chemicals Control Law).

The Chemicals Control Law has as its aim the protection of "man and his environment against risks which may arise from chemicals ..." (3). The Act does not name an administering body. The measures for implementing the Act are to be laid down in Decrees made in the Conseil d' Etat (4).

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(1) McLoughlin and Forster (1982), p. 12.

(2) An English copy may be found at (Reference) Int'l Env. Rep. (BNA) 231 : 5001 (1978).

(3) Section 1.

Decree No. 79-35 of January 15, 1979 On the Control of Chemicals was issued through the Ministry of the Environment (5) so as to implement the general provisions of Law No. 77-771. The Decree covered the details of the notification process, test requirements, confidentiality, etc. It came into effect six months following its publication.

Order of May 28, 1979 was issued by the Minister for the Environment and the Minister for Health and the Family (6). The Order concerns the technical documents to be supplied prior to the manufacture of a new chemical. It details the information required in the technical information dossier referred to in Decree No. 79-35 for different quantities of chemical produced or imported.

Under the French scheme, the Law, Decree and Order provide increasingly detailed requirements for the notification process for new chemicals. All of these predate the Sixth Amendment of September 28, 1979. It was more than three years after the Sixth Amendment that the French laws were amended to conform with the Sixth Amendment. The legislative history of the amendment of French law has been briefly outlined elsewhere (7).

Amendment No. 82-905 of October 21, 1982 (8) amended the Chemical Control Law so that notification from other EEC countries would have legal effect in France, that a ban on dangerous substances may be "total" instead of "temporary", and that some information is not to be considered confidential.

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(4) Section 16.

(5) (35/NCP/ENV/79.2).

(6) (36/NCP/ENV/79.1); published in the Journal Officiel de la Republique Francaise, September 28, 1979, p. 8164.

(7) "France: measure passed to make toxics law conform with Sixth Amendment Directive", (Current) Int'l Env. Rep. 5 : 436-437 (1982).

(8) Law No. 82-905 of October 21, 1982, Journal Officiel de la Republique Francaise, Edition des Lois et Decrets, October 22, 1982, No. 247, pp. 3194-3195. An edited English version may be found at Int'l D. of Health Leg. 34 : 128-30 (1983).

The situation in France is complicated by the fact that there is a parallel system operating with that outlined above. The Ministry of Labour administers the Safety at Work Law of December 1976. This Law has a minor portion which is concerned with new chemicals in the workplace. A Decree and Order implementing the Law have come into effect (9). The notification requirements under the Safety at Work Law were different from Law No. 77-771. However, Law No. 82-905 amended both Law No. 77-771 and the Safety at Work Law.

Recently France has issued Instructions on good laboratory practice, based largely on the OECD Principles of GLP (10). Also within the last year, an Order has been issued setting out the composition and working procedures of the Commission for the Assessment of the Ecotoxicity of Chemical Substances (11).

It is fair to say that the French system is more confusing than those of the other Member States (with the possible exception of the Netherlands for other reasons) because implementation of the Sixth Amendment has been effected through so many different statutory instruments. The French experience shows what happens to those who are first to pass laws during a reform movement - forever after they must amend and revise their initial legislation to keep up with the momentum of the movement. Those who enter the game late can do so with a single, coherent piece of legislation.

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(9) Unfortunately a full English version of the Safety at Work Law and its Decree and Order are not readily available.

(10) Instructions of May 31, 1983 On Good Laboratory Practice (GLP) With Regard to Experimental Toxicology, Bulletin Officiel du Ministere des Affaires Socials et de la Solidarite Nationale et du Secretariat d'Etat Charge de la Sante, July 16, 1983, No. 83/25, Text No. 1065, 16 pp. The Instructions are noted in Int'l Dig. of Health Leg. 34 : 868 (1983) but a full English version is not readily available.

(11) Order of June 10, 1983 On the Composition and Working Procedures of the Commission for the Assessment of the Ecotoxicity of Chemical Substances, Journal Officiel de la Republique Francaise, Edition des Lois et Decrets, June 25, 1983, Supplementary Issue No. 146, pp. 5823-5824. The Order is noted in Int'l Dig. of Health Leg. 34 : 868 (1983) but a full English version is not readily available. Note also the earlier Decree No. 81-278 of March 25, 1981 Establishing an Interministerial Group on Chemical Products, Journal Officiel de la Republique Francaise, Edition des Lois et Decrets, March 27, 1981, No. 73, p. 881. This was issued pursuant to Law No. 77-771. It was noted in Int'l Dig. of Health Leg. 32 : 813 (1981). A full English version is not readily available.

Status of Implementation

French law was amended to comply with the Sixth Amendment on October 21, 1982. France has the requisite administrative structures in place for handling the notification material (12).

Purpose or Scope of the Legislation

Law No. 77-771 expressly states that the aim of the legislation is to protect man and the environment against risks which may arise from chemicals (13). The Safety at Work Law is not readily available, but presumably its purpose is concerned with the risk to human health posed by chemicals in the workplace.

Effective Date of Notification Requirement

While Law No. 77-771 came into effect on July 12, 1977, the Law could not be implemented until Decrees under the Law were made. Decree No. 79-35 of January 15, 1979, implementing Law No. 77-771, came into effect on July 1, 1979 (14). Notification for new chemicals under the Safety at Work Law came into effect October 1, 1979, three months later.

Type of Notification

Law No. 77-771, as amended by Law No. 82-905, states that producers and importers must notify the competent authority in France before marketing any chemical substance that has not been marketed in the EEC prior to September 18, 1981 (unless it has been marketed elsewhere in the EEC under laws conforming to the 6th Amendment) (15). The previous section 3 was a premanufacturing/preimporting notification. The new section 3 states that "the importation of a substance originating from a State that is not a Member State of the European Communities shall be considered as marketing". This means that a company can manufacture a new chemical in France and store it indefinitely without notifying the government - as long as it was not marketed - but the company could not import a chemical from Canada, for example, and similarly store it without notification. The notification would have to occur 45 days before the chemical was imported. In practice, would this frequently mean notification to the French government before chemical left Canada?

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(12) Morlet (1982).

(13) Section I of Law No. 77-771.

(14) Section 16, Decree 79-35 of January 15, 1979.

Time of Notification

Law No. 77-771, as amended by Law No. 82-905, states that where notification is required, a substance may be marketed only 45 days after the date of notification (16). This is a change from the previous time period of one month. Notification is "complete notification", that is, the 45 days does not begin to run until the technical dossier is delivered. As in the Sixth Amendment, the competent authority does not "licence" or "approve" upon receipt of a notification, but acts if it appears necessary to prevent danger to man or the environment.

Responsibility for Notification

The producer or importer has the responsibility to notify the competent authority prior to the marketing of a chemical substance (17). The law does not deal with potential legal questions such as who is the "importer"? - that term is not defined. What would be the status of subsidiaries or local agents?

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(15) Section 3 of Law No. 77-771, as amended by Law No. 89-905.

(16) Section 4 of Law No. 77-771, as amended by Law No. 89-905.

(17) Section 3 of Law No. 77-771, as amended by Law No. 89-905.

Notification Authority

Law No. 77-771 refers to the "appropriate administrative authority (section 3,4,5 etc.). The amending Law No. 82-905 refers to the "competent administrative authority". Decree No. 79-35 predates Law No. 82-905 and some of the provisions therein will have to be amended. However, the Decree provides that the declaration referred to in the old section 3 is to be sent to the Minister for the Environment (18). Copies of the technical dossier to accompany the declaration are to be sent to the Minister for Industry and the Minister for Health. Relevant documents in the dossier are to be sent to the Minister responsible for transport (19). One source (20) states that there are two competent authorities in France, the INRS (Institute Nationale de la Recherche et de Securite) and the Ministere de l'Environment, Direction de la Prevention des Pollution, Mission du Controle des Produits. A second source (21) indicates that the Ministry of Environmental Affairs is the notification authority under Law No. 77-771 and INRS (National Institute for Research and Safety) under the Safety at Work Law (22). As mentioned supra, a Commission has been established to assess the ecotoxicity of chemical substances (23).

Chemicals to be Notified

All chemicals, whether "natural" or synthetic, pure or in preparations are to be reported, except for(24):

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(18) Section 1, Decree 79-35 of January 15, 1979.

(19) Section 7, Decree 79-35 of January 15, 1979.

(20) Springborn (1982), section on France (no page nos.).

(21) Government Institutes, Inc. (1983) p. V-30.

(22) The European Community Information Service (1982) indicates there are two competent authorities as in footnote (12).

(23) See footnote (11).

(24) Section 2 of Law No. 77-771, as amended by Law No. 82-905.

(a) chemicals used for research or analytical purposes (to be defined by Decree);

(b) chemicals to be used for:
  - medicine
  - cosmetics and toiletries
  - food-contact materials (and products used to clean the latter)
  - agricultural pesticides
  - fertilizers
  - explosives
  - food additives
  - (generally if regulated elsewhere);

(c) radioactive substances.

Exemptions

Notification is not required of the following:

(a) EEC exemption - if the substance is imported from another Member State and it has been marketed in accordance with national rules made to implement the Sixth Amendment (25).

(b) Polymer exemption - polymers, polycondensates and poly-addition products differing from already existing products only by their molecular weight are not new chemicals. A macromolecular chemical is only "new", and requires notification, if at least one new chemical enters its chemical composition and represents more than 2% by weight of the final composition (26).

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(25) Section 3 of Law No. 77-771, as amended by law No. 82-905.

(26) Article 4 of the Order of May 28, 1979.

(c) Ten year exemption - if the substance was notified "properly in a Member State of the European Community at least ten years ago", the technical dossier is not required (27). Note that this is a partial exemption in most other Member States in that some data is required.

Inventory

The EEC inventory system is not directly referred to in the French legislation. However, the notification provision (28) states that notification is only required for chemicals not marketed in a Member State prior to September 18, 1981. Presumably this provision will be amended to include reference to the EINECS inventory when it is published in 1985. There does not appear to be a separate French inventory.

Content of Notification

Full notification requires the submission of a technical dossier providing data "for the assessment of foreseeable immediate or delayed hazards and risks that the substance may cause to man and his environment" (29). Both Decree No. 79-35 and Order of May 28, 1979 list the specific contents of the dossier. The Order is more particular. It essentially follows the details of Annex VII of the Sixth Amendment, but there are differences (30). Law No. 82-905 requires the submission of a declaration and proposals for preventative measures to be taken (31).

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(27) Section 3 of Law No. 77-771, amended by Law. No. 82-905.

(28) Ibid.

(29) Section 3 of Law No. 77-771, as amended by Law No. 82-905.

(30) For example, under "identity of the substance", the French requirements delete CAS number. There are few substantive differences, one of which might be the French requirements for identification of environments in which the chemical and its by-products end up.

(31) Section 3 of Law No. 77-771, as amended by Law No. 82-905.

Testing Requirement

The technical dossier required by the amended Law No. 77-771 must contain the results of the tests outlined in the Order of May 28, 1979, reproducing almost intact the requirements of Annex VII of the Sixth Amendment. Chapter II of that Order requires that the tests be carried out in accordance with "official methods", AFNOR standards or equivalents. New methods must be substantitated. Tests must be carried out in compliance with existing laboratory practice rules, as recommended by "the competent international organizations" (32).

Mutual Acceptance of Data

As mentioned, notification is not required if the substance has been marketed elsewhere in the EEC in accordance with the Sixth Amendment (33). There is a further provision that the technical dossier will not be required in the case of chemical substances which have been duly notified in a Member State for at least ten years. The difference between these two provisions is that the latter covers the case where a substance has been notified in another Member State but has not been marketed there. Perhaps this alleviates the fear that an importer into the EEC will pick the Member State with the least effective competent authority to introduce a new chemical, and then export to other Member States. This provision will tend to force importers to notify the Member State in which they actually intend to market the new chemical.

There is no express reference to the transfer of dossiers or summaries of dossiers as there is, for example, in the U.K. legislation.

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(32) Implying, most likely, the OECD guidelines.

(33) Section 3 of Law No. 77-771, as amended by Law No. 82-905.

Flexibility in Notification Requirements

The notification process is open-ended. Every producer or importer must keep the administrative authority informed in changes (34):

(a) in the quantities marketed as compared with the notified shcedule;

(b) in new uses of the substance resulting, in particular, from its incorporation in preparations;

(c) new facts, emerging either from scientific/technical advances or from observations of the effects of the substance.

Is there flexibility in the information requirements in different circumstances? If the notifier is unable to complete some of the sections in the dossier "or thinks they are irrelevant to his particular case", he must state the reasons for this and undertake to supply the missing information as soon as those reasons cease to apply (35).

There are provisions allowing the notifier to submit a dossier with only part of the total requirements of Annex VII of the Sixth Amendment:

(a) Quantity less than one tonne per year - if a chemical is to be manufactured or imported in quantities less than one tonne per year per producer or importer, the dossier may be confined to:
   (i) names of substance;
   (ii) formulae;
   (iii) uses;
   (iv) quantities;
   (v) proposed precautions;
   (vi) emergency measures (human injury) (36).

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(34) A new section, 5 bis, added to Law No. 77-771 by Law No. 82-905.

(35) Section B of the Order of May 28, 1979.

(36) Article 2 of of the Order of May 28, 1979.

This relieves the notifier of supplying data on physico-chemical properties, toxicology, ecotoxicology, and disposal measures.

(b) Quantity more than 100 tonnes - if the quantity produced or imported is greater than 100 tonnes per year producer or importer, or if the conditions of use are likely to lead to considerable human exposure, the subacute or cumulative acute toxicity tests are compulsory. For quantities less than 100 tonnes the tests are not compulsory (37).

Follow-up Measures/Further Testing

As mentioned (38), producers and importers must keep the competent authorities informed of changes in circumstances. The competent authorities may require such persons to furnish such technical dossiers "as are necessary for the re-examination of the substance" (39).

Upon receipt of the dossier, the competent authority may enter the substance on a list of products dangerous to man and the environment (40).

Special Orders

Regardless of whether or not a substance is included on a "dangerous substance" list, the marketing of chemicals may be subject to conditions (41). These conditions imposed on producers or importers may be one or more of the following obligations:

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(37) Article 3 of the Order of May 28, 1979.

(38) Footnote (32).

(39) Ibid.

(40) Section 4, Law No. 77-771.

(41) Section 5 of Law No. 77-771, as amended by Law No. 82-905.

(a) inform the competent authority of the composition of preparations containing the chemical;

(b) provide samples of the substance or its preparations;

(c) supply data on quantities marketed, broken down by use;

(d) provide any additional information on the effects of the substance
on man and the environment.

Protection of Confidential Data

Section 6 of the Chemical Control Law obliges the government to maintain the confidentiality of the information supplied to it through the notification system. This provision was revised so as to make explicit which data are not to be protected as trade secrets (42).

The list of non-confidential information is as follows:

(a) commercial name;

(b) physico-chemical data;

(c) ways of rendering the substance harmless;

(c) interpretation of toxicological and ecotoxicological tests as well as the name of the agency responsible for the tests;

(e) methods and precautions recommended for handling, storage, transportation, fire, or any other peril;

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(42) Article 6 of Law No. 82-905.

(f) emergency measures to take in case of accidental spills and personal accidents.

The notifier must request confidentiality and must provide justification. If he later discloses the data he must inform the competent authority (43).

The amended confidentiality provision anticipates that a Decree will be issued establishing the conditions for protection of confidentiality of an entire formula of preparations, particularly in the case of centres for treatment of poisoning.

Disclosure of Data and Proprietary Rights

The amended Law No. 77-771 provides that the competent authority may communicate to the EEC Commission any information required for enforcement of Community obligations. As well, the provision contemplates that a Decree will establish means of public access to non-confidential data (44).

Public Participation

Other than the contemplated Decree providing public access to non-confidential data, the French legislation does not provide for public participation.

Enforcement and Penalties

The penalty provisions in Law No. 77-771 were amended by Law No. 82-905 so as to rephrase the possible offences which may be committed. These include failure to provide notification, failure to respect the 45 day notification period, failure to provide other required information, etc. (45).

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(43) Ibid.

(44) Ibid.

The actual penalty provisions in Law No. 77-771 remain unchanged. Failure to notify may result in a fine of 1,000 to 30,000 Frs. while other offences may result in a fine of 2,000 to 500,000 Frs. and/or imprisonment for two months to two years.

Various search and seizure powers are provided for in Law No. 77-771.

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(45) Section 10 of Law No. 77-771, as amended by Article 8 of Law No. 82-905.

2.4 GERMANY

The Federal Republic of Germany, or West Germany, is a federal state. The Constitution gives the eleven states (Lander or Land authorities) equal status with the Federal Government (Bund). Legislative authority is divided between the Federal Government and the Lander. With respect to poisonous substances and trade regulations the Federal Government and the Lander have concurrent jurisdiction, but the Lander may only pass laws in these areas if the Federal Government has not done so (1). West Berlin has a special status, not being subject to the Federal Government, but the West Berlin Parliament usually gives formal acceptance to federal laws (2).

Germany has separate legislative, executive and judicial branches of government. The Federal Chancellor is the most powerful figure in the Federal Government. He is head of the Executive Branch and is elected from among members of the lower house of parliament (Bundestag) by that body. He selects the candidates for appointment as heads of the federal ministeries. The legislative branch consists of the popularly elected lower house, the Bundestag, and the appointed Federal Council, the Bundesrat. The latter represents the Lander governments (3).

Legislation is drafted by the Executive Branch. It is submitted to the Bundesrat so that objections by the Lander may be considered before the bill is formally introduced to the Bundestag. After introduction there, the bill is sent to committee for review. After the Bundestag passes the bill, it must go to the Bundesrat for concurrence or veto (4). This arrangement is an interesting way to balance federal and regional interests. It is quite different from the Canadian situation, but is similar to many of the proposals which have been made to reform the Canadian Senate into a "House of the Provinces".

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(1) (Reference) Int'l Env. Rep. 241 : 0101 (1983).

(2) McLoughlin and Forster (1982), p. 15. If this authority is right on this point it is strange that Article 30 of the Chemicals Law would state "This Act shall also be applicable in Land Berlin in accordance with Article 13, Para. 1 of the Third Transitional Law".

(3) Footnote (1).

(4) Ibid. Approval by the Bundesrat is necessary for legislation such as the Chemicals Law. Laws which do not affect the Lander (eg. foreign affairs) do not require the Bundesrat's approval. Dr. Broecker (pers. comm.)

As in most countries, no federal department acts exclusively in the area of environmental protection. The Federal Government may legislate on economic matters, the handling of toxic substances and on technical protection of workers in the work place (5). While over ten departments are involved in environmental protection, it is the Federal Ministry for Youth, Family Affairs and Health which is generally responsible for toxic substances and human health (6).

Overview

Germany has implemented the EEC Sixth Amendment with the Act on Protection Against Dangerous Substances (7), commonly referred to as the Chemicals Act.

Germany's new chemical notification system is administered by the federal Office for Occupational and Safety Policy (Bundesanstalt fur Arbeitsschutz und Unfallforschung) (BAU). This agency is under the supervision of the Ministry for Youth, Family and Health (8). Summaries of notifications must be sent to the Lander. Three other agencies are involved in the evaluation process:

a) The Federal Environmental Protection Agency;
b) The Federal Health Agency;
c) The Federal Institute for Labour Protection and Accident Research.

In some respects, the Chemicals Act is more stringent than the requirements of the Sixth Amendment. For example, notification may be required for some existing substances as well as new chemicals (9). It is a very comprehensive piece of legislation. Its place in the framework of legislative controls now in force in Germany for a variety of environmental chemicals has been reviewed (10).

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(5) Legislative competence in these three areas is based on: 1) Art. 74, No. 11 Basic Law; 2) Art. 74, No. 19 Basic Law; and Art. 74, No. 12 Basic Law, respectively. Springborn (1982).

(6) Footnote (1) at p 241 : 0102.

(7) Act on Protection Against Dangerous Substances (Chemicals Act) of September 16, 1980. (Federal Law Gazette (Bundesgesetzblatt) I, p. 1718). Published in (Reference) Int'l Env. Rep. 241 : 4101-4108 (1981) and in condensed form in Int'l Dig. of Health Leg. 32 : 515-533 (1981). A breif summary appears in IRPTC Bull. 4 : 24 (1981). A summary and schematic presentation of the legislation has been published, Schmidt-Bleek and Storm (1982).

(8) Footnote (1) at 241 : 0104.

Germany's federal nature is reflected in the operation of the Chemicals Act. For example, the Act requires the Federal Government to seek the consent of the Bundesrat (representing regional interests - the Lander) before issuing certain ordinances which affect them (11). As well, along with its other duties, the notification authority must send a summary of the notification material to the Land authorities and inform them of the results of the evaluation of the submitted material (12). The Land Authorities may also have significant monitoring and enforcement powers under the Act (13).

Status of Implementation

The German Chemicals Act came into effect January 1, 1982 in its entirety, although the provisions of the Act authorizing the issuance of statutory ordinances came into effect in September of 1980 (14). Several implementing Ordinances were issued within the last month of 1981 so as to meet the January 1st effective date (15).

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(9) Article 4, para. 6. See footnote (32) infra.

(10) Rehbinder (1981).

(11) Article 12 relating to the establishment of the notification authority and Article 19 concerning industrial measures such as work practices and layout of the place of work.

(12) Article 12, item 1.

(13) Articles 21 and 23.

(14) Article 31 of the Chemicals Act, 1980. The new Act annulled the Act Concerning Inflammable and Harmful Industrial Materials, Article 29.

(15) See Appendix I.

Purpose or Scope of the Legislation

Unlike the legislation of many of the other EEC Member States, the German Act has a threefold purpose: to protect the environment, human health in general and, specifically, protection of workers at the workplace (16).

Effective Date of Notification Requirement

As of January 1, 1982, notification of chemicals has been required.

Type of Notification

The notification is a form of premarketing notification, although the Act does not use those words. The manufacturer may not put a chemical "into initial circulation" until 45 days have elapsed since notification.

"Putting into circulation" is a defined phrase meaning "keeping on hand for the purpose of selling or disposing of in other ways ... " (17).

An "introducer" may only bring a chemical into the country from a non-EEC country if it notifies the authorities at least 45 days beforehand. This is not a premarket notice but a pre-import notice. Bringing the chemical into the country must be in a commercial or business context, but this is not necessarily the same as marketing. "Introducer" is a defined term, meaning the entity bringing the chemical into the country; excluding those who "only carry out a transit movement under customs supervision" (and provided the substance is not processed) (18). Henceforth, we will use the term "importer" instead of "introducer".

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(16) Although Article 1 of the Act refers to the protection of "man and the environment", the administrative system for the evaluation of submitted information ensures that input will come from agencies involved with the environment, human health and labour. Moreover, there are specific provisions in the Act directed toward occupational health and safety.

(17) Article 3, item 7.

(18) Article 3, item 6.

A manufacturer must give notice if the substance is put into initial circulation "in a country which is a member of the European Communities" (19). Therefore a company in Germany planning to make a chemical solely for marketing in France would have to notify the competent authority 45 days before "keeping it on hand for the purpose of selling" it in France. This reflects the Sixth Amendment view of the EEC as one market. Exports solely to countries outside the EEC do not require notification.

Notification Time Period

Notification must occur 45 days before marketing or importing (20).

Responsibility for Notification

Manufacturers or introducers (importers) are responsible for notification (21). A manufacturer is a natural person or corporate body that manufacturers or "wins" a substance or a preparation (22). There is no mention of what "win" means (23).

The meaning of "introducer" has been discussed supra.

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(19) Article 4, para. 1.

(20) Article 4, paras. 1 and 2.

(21) Ibid.

(22) Article 3, para. 5.

(23) To "win" is similar to "produce" - Dr. Broecker (pers. comm.). However, one author, in the employ of the federal Environmental Protection Agency, refers to an entity who "manufactures or obtains a substance or brings it into the area of validity of the Act". If "to win" means "to obtain" then the Chemicals Act is broad indeed. Schmidt-Bleek and Storm (1982).

An interesting provision in the German Act prohibits importing of chemicals into Germany on a commercial basis by those who are not "domiciled" in a Member State of the EEC (24). Assuming that the translation from the German is accurate and "domicile" is intended instead of "residence" (the two are sometimes confused), then this poses a stringent requirement for importers. Domicile, in Anglo-Canadian law, means permanent residence, that is, residence plus the intention of remaining (25). This provision is undoubtedly a measure aimed at ensuring control over otherwise transient importers from outside the EEC. Non-EEC "importers" must therefore act through an EEC entity which will act as the legal importer. This prohibition does not apply if the substance is in the inventory of substances in circulation in the EEC before September 18, 1981.

Notification Authority

The Chemicals Act states that the notification authority shall be determined by the Federal Government by means of a statutory ordinance requiring the consent of the Bundesrat (26). One source indicates that during 1981, five implementing regulations were adopted, one of which provided for the designation of the competent authority (27). An English copy of this particular ordinance is not readily available. One source indicates that the Federal Office for Occupational and Safety Policy (BAU) is the competent authority for receiving notifications and that subsequent assessment of the notifications is done by BAU (occupational health and safety), the Federal Office for Public Health (health aspects), and the Federal Environmental Protection Agency (environmental aspects) (28).

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(24) Article 4, para. 3.

(25) Osborne's Concise Law Dictionary, 6th ed., J. Burke (ed.), London: Sweet & Maxwell (1976), p. 124.

(26) Article 12.

(27) (Reference) Int'l Env. Rep. 241 : 0104 (1983). The other four ordinances concern:
- a) notification requirements;
- b) inventory of existing substances;
- c) labelling of hazardous substances;
- d) general administration.

(28) Dr. Broecker (pers. comm.).

Chemicals to be Notified

Notification is required for the manufacture or importing of a substance, either as such or as a constituent in a preparation (29). A substance is a chemical element or a chemical compound, not further worked or processed, including any impurities and any additives required for the purpose of placing it on the market (30). "Preparation" is also a defined term (31).

There are provisions for the notification of existing chemicals if they are found to be dangerous (32).

The Act's notification provisions do not directly distinguish between "new" and "existing" chemicals. Rather, there is an exemption from notification if the chemical is on a list published by the Federal Government by ordinance. This ordinance specifies substances in circulation in the EEC before September 18, 1981 (33). So, in effect, notification is required for new chemicals, those put into circulation in the EEC after September 17, 1981. There is no mention of amendment of this list (which presumably is the EEC inventory other Member States will be using) so a substance continues to be "new" even if it has previously been manufactured or imported after September of 1981 (34).

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(29) Article 4, paras. 1 and 2.

(30) Article 3, item 1.

(31) Article 3, item 2 ... "a mixture or solution composed of two or more substances, not further worked or processed, including any impurities and any additives required for the purpose of placing it on the market."

(32) Article 4, para. 6. An existing chemical, one which was in circulation in the EEC prior to September 18, 1981, for which there are grounds for suspecting it is "dangerous", after expert review and by ordinance, may be prescribed - and it may be required to be notified along with test documents. For this provision, a "dangerous existing chemical" is one which is "very toxic, toxic, carcinogenic, teratogenic, mutagenic" or has other "extremely harmful properties", Article 3, items 3(a)(b)(k)(l)(m) or (n). There are many provisions in the Act regarding "dangerous substances" which are not reviewed in this survey. An ordinance has been issued setting out tests results which dictate hazard designations - see Appendix. The authority to require notification of existing chemicals has not been used so far - Dr. Broecker (pers. comm.).

However, a substance may be "new" for other manufacturers or importers but may not be new for subsequent manufacture or import by the original notifier because notice is required when the substance is initially put into circulation or imported (35).

The notification provisions of the Act do not apply to substances which are (36):

- foodstuffs, tobacco products and cosmetic agents
- animal feedstuffs and additives
- pharmaceuticals
- wastes
- radioactive wastes
- waste water
- waste oils
- plant protection products

It is a measure of the comprehensive nature of the Chemicals Act that some provisions not relating to notification may apply to some of the above-mentioned groups of substances.

Total Exemptions

Notification is not required of the following:

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(33) Article 4, paras. 4 and 5.

(34) This will only be true until 10 years have elapsed since the substance was first notified, then it will no longer be "new", Article 5 para. 2 ... see infra under "Exemptions".

(35) Article 4, paras. 1 and 2.

(36) Article 2

(a) EEC exemption - if the substance is notified according to an "equivalent procedure" in another Member State before being manufactured in or imported into that other Member State (37). This is valid only for the same manufacturer or importer.

(b) Non-commercial exemption - if the substance was manufactured or imported other than on a commercial basis "or within the framework of any other business undertaking" (38).

(c) Research exemption - if a chemical is used exclusively in a laboratory it is totally exempt from notification (39).

(d) Polymer exemption - if the substance is a polymer, polycondensate or polyadduct which contains in combined form no more than 2% of a "new" monomer (40), provided the monomer itself is not "very toxic" or "toxic" (41). All combinations, whether new or not, of existing monomers are exempt.

(e) On-site exemption - there is no such exemption clearly stated in the Act. However, a close examination of the notification provisions and the definition of "putting into circulation" suggests that if a manufacturer makes a new substance but does not keep it on hand for the purpose of selling or passing on to others, then notification is not required. In other words, if the substance is used on-site, in the manufacturer's factory, it need not be notified. This possibility indicates the significant distinction between a pre-manufacturing and a pre-marketing notification system.

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(37) Article 4, paras. 1 and 2.

(38) Ibid.

(39) Article 16, para. 3.

(40) Article 5, para. 1, item 1.

(41) Article 16, para. 5 - in which case notification of recommendations on precautionary and emergency measures and proposed classification must be given in accordance with Article 6, para. 2. There is no obligation to test whether a new monomer is toxic.

Partial Exemptions

Some substances are subject to limited notification procedures:

(a) Testing exemption - if the substance is passed on to others by the manufacturer or importer for "the sole purpose of investigating or testing its properties or further development of it". However, this applies for a one year period of testing, unless the testing is for the purpose of determining the substance's dangerous properties. As well, the persons doing the testing must be proven to be qualified (42).

(b) Quantity exemption - if the substance is to be put into circulation by the manufacturer or importer in quantities of less than one tonne per year (43).

What is required to be notified in the case of a testing or quantity exemption as outlined above? Nothing if the substance is to be used exclusively in a laboratory (44). Otherwise, the following information must be supplied to the competent authority (45):

(i) the subtance's identifying features;
(ii) the intended labelling;
(iii) intended quantity to be put into circulation annually;
(iv) in the case of testing, information regarding the receipient, if requested.

Note, however, that for partially exempt chemicals, test data is not required. If it is submitted on a voluntary basis, test data will be taken into account for labelling.

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(42) Article 5, para. 1, item 2.

(43) Article 5, para. 1, item 3.

(44) See *supra* with respect to research exemption. It is noted that the Act does not actually use the phrase "research exemption".

(45) Article 16, para. 3. Note that this information must be notified in writing beforehand; ie: not 45 days before putting the substance into circulation.

(c) Ten year exemption - if a substance has been notified by another manufacturer or importer, if more than ten years have elapsed since the initial notification (46).

While an initial notifier may have complied with all notification requirements, a subsequent notifier only has to do so for ten years, after which a subsequent notifier, when putting a substance into circulation for the first time (for that notifier), must submit only the following to the competent authority (47):

- (i) the identifying features;
- (ii) details on the utilization;
- (iii) harmful effects during the utilization;
- (iv) quantities proposed to be put into circulation;
- (v) if a dangerous substance, recommendations on precautionary and emergency measures, classification and labelling;
- (vi) physico-chemical properties;
- (vii) impurities and "auxiliary agents";
- (viii) known decomposition products.

Inventory

The Federal Government is required by the Chemicals Act to specify, by ordinance, the substances in circulation in the EEC prior to September 18, 1981 (48). Such an ordinance came into effect on December 2, 1981 with an Annex attached listing the pre-September 1981 substances for which notification is not required (49), unless there are grounds for suspecting the substance is dangerous (50).

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(46) Article 5, para. 2. This applies whether the initial notifiction was given in Germany or another Member State as long as equivalent notification procedures were followed.

(47) Article 16, para. 4 refers to Article 6, para. 1, items 1 to 4, para. 2 and Article 7, para. 1, item 1. Note, however, that further testing will be required if levels reach 100/500 tonnes and 1000/5000 tonnes as discussed infra in the section "Further Testing Requirements".

(48) Article 4, para. 5.

Content of Notification

The Act sets out the categories of information which must be submitted to the competent authority (51). These categories have been expanded by ordinance (52) to conform with the details of Annex VII of the Sixth Amendment. The basic categories of information are as follows:

- (a) name and address of notifier;
- (b) the identifying features of the substance;
- (c) details on the utilization;
- (d) harmful effects during the utilization;
- (e) the quantities of the substance proposed to be put into circulation annually;
- (f) disposal, recycling (if possible) and neutralizing methods;
- (g) test documents;
- (h) if a dangerous substance, recommendations on precautionary measures in the event of accidents and proposed classification (in accordance with statutory ordinance), packaging and labelling (53).

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(49) The Chemicals (Existing Substances) Ordinance of December 2, 1981, Bundesgesetzblatt, Part I, December 10, 1981, No. 51, p. 1239.

(50) See footnote (32). The German inventory mentioned is for the time being only the ECOIN. The EINECS will be adopted when available.

(51) Article 6, paras. 1 and 2.

(52) The Chemicals Law Notification and Test Data Ordinance of November 30, 1981, Bundesgesetzblatt, Part I, December 10, 1981, No. 51, pp. 1234-1236.

(53) This information may not be submitted, as well as that in item (d), if the substance has been classified by the statutory ordinance - Article 6, para. 3 and Article 13, para. 3.

Testing Requirements

The test documents submitted with the notification must "enable a judgement to be made on whether the substance ... has harmful effects on man or the environment" (54). The methods and results of the following tests must be submitted:

(a) physico-chemical properties;
(b) auxiliary agents and major impurities;
(c) known decomposition products;
(d) acute toxicity test;
(e) carcinogenic or mutagenic test;
(f) corrosive, irritative, sensitization test;
(g) subacute toxicity test;
(h) environmental test.

These tests can be considered a "base set". Further tests may be required depending on the quantity of the substance put into circulation, as discussed, infra.

Mutual Acceptance of Data

The notification provisions of the Chemicals Act do not require notification if the substance was notified by an "equivalent procedure" in another EEC Member State, before being put into circulation or imported (55).

The competent authority is responsible for informing a manufacturer or importer, if a legitimate request is made, whether a specific substance has been previously notified in Germany or elsewhere in the EEC (56).

The competent authority is also responsible for forwarding a summary of information submitted to it to the Commission of the European Communities. Full documentation may also be sent, but the notifier will be consulted regarding confidential data in the material. Member States may receive the information on request but only if they have measures in place to protect confidential data (57).

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(54) Article 7, para. 1.; See generally Schmidt-Bleek and Lange (1983).

(55) Article 4, paras. 1 and 2.

(56) Article 12, para. 1, item 2.

Flexibility in Notification Requirements

The base test documents listed in the previous section do not have to be submitted if testing of the substance is "technically impossible or unnecessary in view of the state-of-the-art of scientific knowledge". However, the notifier must give the grounds for non-submission (58).

Further tests may be required if the quantity of substance put into circulation reaches certain levels. It is important to note that the German Act states that the notification authority "can demand" documentation of further tests (59). It does not state "must" or "shall". Discretion will presumably be applied in the administration of the Act in a manner as set out in the Annex of the Sixth Amendment.

The further testing requirements are as follows:

(a) 100 tonnes/500 tonnes (60) - if the notifier puts 100 tonnes per year into circulation in the EEC, or if 500 tonnes, in total, have been put into circulation in the EEC since the substance was first put into circulation in the EEC then documentation of the following tests can be demanded:

  (i) subchronic toxicity;
  (ii) impairment of fertility;
  (iii) environment test;
  (iv) carcinogenic, mutagenic, and teratogenic properties.

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(57) Article 12, para. 1, item 3.

(58) Article 7, para. 2.

(59) Article 9, para. 1.

(60) Article 9, para. 1, item 1.

(b) 1000 tonnes/5000 tonnes (61) - similarly, the following can be demanded:

- (i) biotransformation and toxicokinetic properties;
- (ii) chronic toxicity;
- (iii) carcinogenic properties;
- (iv) acute and subacute toxicity (62);
- (v) behaviour-altering properties;
- (vi) properties affecting fertility and teratogenic properties (63);
- (vii) additional environment test (64).

The test documents provided for at the 100/500 and 1000/5000 tonne levels do not have to be submitted if the testing of the substance is technically impossible or unnecessary in view of the state-of-the-art of scientific knowledge - but in such cases the notifier must give grounds for non-submission (65). Details of these tests have been set out by ordinance (66). The Federal Government is authorized to adjust the types of tests required after review (67).

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(61) Article 9, para. 1, item 2.

(62) Insofar as the necessity arises from the test results received from reaching the 100/500 tonne levels or from the behaviour-altering properties test.

(63) Insofar as the necessity arises from the test results received from reaching the 100/500 tonne levels.

(64) By "environment test", for both 100/500 and 1000/5000 tonne levels, the actual phrase is "properties which alone or in conjunction with other properties of the substance are a danger to the environment".

(65) Article 9, para. 1, in reference to Article 7, para. 2.

(66) See footnote (52).

(67) Article 10, para. 3.

Further Testing/Follow-up Measures

The German competent authority has broad powers to demand further information. The test documentation for the 100/500 tonne levels can be demanded if the levels reach 10/50 tonne levels if circumstances suggest there may be a problem (68). Further, the ten year exemption, discussed supra, is subject to the test requirements if levels reach 100/500 tonnes and 1000/5000 tonnes (69).

The competent authority may also demand test documents for any of the tests discussed supra for substances otherwise meeting the testing or quantity exemptions (70). The competent authority may also demand the tests set out for the 100/500 tonne levels before quantities actually reach those levels (71). This does not appear to be the case for the tests set out for the 1000/5000 tonne levels. But for these demands there must be indications that the substance is a potential danger.

The notifier is required to inform the competent authority of (72):

(a) change in utilization;
(b) quantities proposed to be put in circulation or imported each year;
(c) any new findings concerning the effects of the substance on man or the environment;
(d) any change in the properties of the substance;
(e) cessation of production or introduction of the substance;
(f) if quantities reach 10/50, 100/500 or 1000/5000 tonne levels.

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(68) Article 9, para. 2.

(69) Article 9, para. 3.

(70) Article 11, para. 1, item 1.

(71) Article 11, para. 1, item 2.

(72) Article 16, paras. 1 and 2.

Special Orders

The competent authority may impose preconditions on the putting into circulation of any substance otherwise meeting the testing and quantity exemptions discussed supra if there are "real indications that the substance is most probably a potential danger" to health or the environment (73). The Act does not elaborate on specific preconditions which may be contemplated by this provision.

The competent authority may prohibit the putting into circulation of a substance or preparation if the test documentation for the 10/50, 100/500 or 1000/5000 tonne levels, or the further information mentioned in the second paragraph of the above section "Further Testing Requirements" is not submitted to the competent authority within a specified time period (74).

The Federal Government is authorized by the Act to impose bans and restrictions with respect to dangerous substances (75). This may only be done by statutory ordinance and only if the risk to health or the environment cannot be eliminated by classification, packaging and labelling. An outright ban on manufacturing may be issued, or manufacturing and marketing may be restricted by certain conditions for certain purposes. The Act also authorizes the government to make ordinances with respect to the packaging and labelling (76). The Act also provides authority for ordinances of an occupational health and safety nature (77).

Notifiers are required to retain copies of submitted documents for five years (78).

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(73) Article 11, para. 1, item 3.

(74) Article 11, para. 2.

(75) Article 17.

(76) Articles 13 and 14.

(77) Article 19.

(78) Article 20

Protection of Confidential Data

As mentioned, submitted information will not be forwarded by the competent authority to another EEC Member State unless the latter has measures in place to protect confidential data. The competent authority must forward information to the regional Land authorities (79). There is no mention of precautionary measures to be taken by this level of government.

The Chemicals Act provides that if a notifier requests, information which constitutes a manufacturing or trade secret shall be marked as confidential (80). There is no mention of how it will be treated as confidential. The Act does state that the following will not be considered as manufacturing or trade secrets (81).

(a) the trade name of the substance;
(b) the physico-chemical properties;
(c) methods of disposal, recycling, and neutralizing the substance;
(d) recommendations on precautionary and emergency measures, proposed classification, packaging and labelling;
(e) the evaluation of toxicological and ecotoxicological tests and the name of the person responsible for these tests.

Disclosure of Data and Proprietary Rights

Disclosure in relation to EEC requirements has been discussed.

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(79) Article 12, para. 1 and Article 21, para. 2.

(80) Article 12, para. 3. In practice the competent authority will have to accept confidentiality claims of the notifier unless it has a good reason for denying them - Dr. Broecker (pers. comm.).

(81) Article 12, para. 4.

The Act provides that where a substance has previously been notified, the competent authority may allow a subsequent notifier to refer to the results of the tests carried out by one or more previous notifiers if written consent of the previous notifiers is obtained. This applies to the base set of tests and the further tests required if levels reach 100/500 tonnes or 1000/5000 tonnes (82). In practice the government itself will not disclose information to the subsequent notifier. The requirement of written consent presumably offers some protection of proprietary rights. Presumably commercial arrangements between notifiers can be made to obtain written consent. If no agreement is reached a subsequent notifier will have to redo the necessary tests.

Public Participation

As mentioned, some information submitted by the notifier is not considered to be confidential, but there is no apparent mechanism in the Act for releasing that information.

It is not apparent that there is any mechanism for public participation in the decision-making process.

Enforcement and Penalties

The power of the competent authority to make certain orders has been mentioned. There are some monitoring powers given to the Land authorities, essentially giving the Land authority the power to enforce the Act insofar as enforcement powers are not given to the competent authority by the Act or by ordinance (83). The Land authority may request "any information which is required to enforce (the) Act and the statutory ordinances based on (the) Act". They may also "request presentation of the notification and informatio documents" (84). Most of the monitoring provisions, however, appear to be directed toward an occupational health and safety function and toward dangerous substances.

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(82) Article 7, para. 3 and Article 9, para. 1.

(83) Although an ordinance was issued in 1981 for the establishment of the competent authority, an English copy is not readily available. Presumably the ordinance outlines in detail further powers of the competent authority.

The Land authorities can issue "on a case-to-case basis" any orders necessary to correct contraventions or prevent future contraventions of the Act or ordinances (85). This would seem to be a very broad power indeed; no restraints are set out in the Act - perhaps this could not be done for constitutional reasons.

The notification procedure is deemed to be an administrative procedure (86). The failure to comply with the various obligations on the part of the notifier are "administrative offences" (87). Violation of the major obligations in the notification procedures contained in the Act may bring fines of up to 100,000 Deutschmarks. Failure to notify changes in circumstances (as opposed to initial notification) may bring a fine of up to 10,000 Deutschmarks (88).

If an administrative offence is committed and the life or health of another person or the property of significant value belonging another, is endangered, a penalty of imprisonment of up to five years, or a fine, may be imposed (89). This may be considered a "criminal offence".

"Any attempt is punishable" (90) and in cases of negligence a person may face imprisonment for up to two years, or a fine (91).

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(84) Article 21, paras. 2 and 3. No mention is made of measures to protect confidentiality.

(85) Article 23, para. 1.

(86) Article 22.

(87) Article 26, para. 1.

(88) Article 26, para. 2.

(89) Article 27, para. 2.

(90) Article 27, para. 3.

(91) Article 27, para. 4.

2.5 GREECE

Greece is a republic with a written constitution, a Parliament, a President as Head of State and a Prime Minister as head of the executive. The constitution is unusual in that it contains a provision for the protection of the environment. Under the 1975 Constitution the elected Parliament is the supreme legislative power. Decrees may be issued in the President's name within the framework of existing law. Ministers may issue Decisions in accordance with authorising laws. In addition, Ministers may issue Circulars giving guidance on the interpretation of laws, decrees and decisions (1).

Greece became the 10th member of the EEC several years ago. Two years after its accession to the EEC, Greece had incorporated into national law only 20 of 700 EEC Directives. Enforcement had not begun under any of the 20. As of January, 1983, Greece had not implemented the Sixth Amendment and there was some indication that Greece would be brought before the European Court of Justice to account for its failure. There has been concern that Greece would be a "weak gatekeeper" allowing the EEC to be flooded with untested chemical substances (2).

While there is no word whether Greece has recently implemented the Sixth Amendment, in the last year there has been significant new legislation and plans for legislation introduced which have concerned a variety of environmental issues (3). One report has indicated that there is a draft Presidential Decree in existence which, while not yet released to the public, appears to incorporate all but a few of the provisions of the Sixth Amendment (4).

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(1) McLoughlin and Forster (1982).

(2) "EEC May take Greece to Court of Justice for Failing to Implement Sixth Amendment", (Current) Int'l Env. Rep. 6 : 4-5 (1983).

(3) "New Environmental Law to be Offered, Environmental Agency to be Reorganized", (Current) Int'l Env. Rep. 6 : 12-13 (1983); "Draft

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Pesticides Law Would Require Extensive Testing Under Local Conditions", (Current) Int'l Env. Rep. 6 : 98-99 (1983); "New Land Use Law Seen as Major Step in Improving Environmental Conditions", (Current) Int'l Env. Rep. 6 : 208-209 (1983). The OECD has recently published a 1983 document titled "Environmental Policies in Greece" which may outline the Greek difficulties with implementing the Sixth Amendment.

(4) Springborn (1982).

2.6 IRELAND

The "sole and exclusive power" of making laws in Ireland is vested in the Oireachtas, which comprises the President, House of Representatives (Dail), and the Senate. Laws cannot be made inconsistent with the terms of the country's Constitution. Powers of legislation are delegated to Ministers and various subordinate bodies. There are about eight ministries with various environmental responsibilities. The Ministry of Labour appears to handle most responsibilities regarding dangerous substances (1).

Ireland has implemented the Sixth Amendment. While the chemical industry is relatively important in Ireland, with exports worth more than £ 500 million annually (2), a recent report has suggested that Ireland will have difficulties in meeting its obligations under its implementing legislation (3). Apparently there are only 4 toxicologists in Ireland available to assess submitted material under the notification system (and similar recent legislation) and it is estimated that 12 toxicologists will be required to meet EEC commitments. This, despite the fact that only 3-12 new chemical products are developed annually in Ireland and the existence of three potential contract testing laboratories. One of the concerns expressed in the report is that the requirement for qualified staff may be higher than otherwise anticipated because chemical companies outside the EEC may view Ireland as an ineffective "gatekeeper" for the products seeking entry into the EEC. As noted:

> "This is because English is the language preferred by chemical companies for such approval procedures and, because the other two member states using English for this purpose, (UK and the Netherlands) are known to take a strict line in such procedures."

The Irish situation points out two potential problems with notification schemes. First, that legislative demands in themselves may not be effective if a country's scientific infrastructure is not sufficiently developed. One cannot legislate qualified toxicologists into existence overnight (although they can be hired away from other countries). Second, if there is a "mutual acceptance of data" provision in existence - in other words, if a country is a member of a larger multinational notification system, any country seen as a "weak link" or and "easy gatekeeper" can anticipate having its assessment infrastructure swamped by outside parties.

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(1) McLoughlin and Forster (1982).

(2) "Minister of Labour Publishes Regulation Bringing EEC Sixth Amendment into Effect", (Current) Int'l Env. Rep. 6 : 47-48 (1983).

(3) "Board says Ireland Cannot Meet Obligations to Test New Chemicals Under EEC Directives", (Current) Int'l Env. Rep. 6 : 209 (1983).

If a country has a poorly developed infrastructure will there be an inclination not to require further testing or information on the part of notifiers?

A review of complementary legislation in Ireland regulating chemicals has been published (4).

Overview

Is the Irish legislation less strict than that of other EEC Member States? Answers to questions of this nature are often difficult to answer through a simple review of the wording of legislation. This is because the procedures and policies adopted in the administration of legislation are often more important in determining whether the legislation is "tough" or "soft" than the legislation itself.

One significant point is that a violation of the implementing legislation is subject only to a 600 fine. The regulations were made pursuant to the Irish European Communities Act 1972 which prohibits the creation of indictable offenses in regulations made under the Act. If a breach of any of the provisions of the Irish notification system is a minor infraction, how will this affect the cost-benefit analysis of entities not inclined to be "good corporate citizens"?

The Irish legislation follows the Sixth Amendment so closely that, unlike other countries, it adopts by reference various provisions of the EEC Directive. In fact, one cannot follow the Irish legislation without a copy of the Directive alongside.

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(4) Scannell (1980). This review does not, of course, cover the Irish implementation of the Sixth Amendment in 1982.

Status of Implementation

In 1982 regulations were made by the Minister for Labour to implement the Sixth Amendment. They were made pursuant to the European Communities Act, 1972 (5). The regulations, cited as the European Communities (Dangerous Substances) (Classification, Packaging, Labelling and Notification) Regulations, 1982 (6), will be referred to as the Notification Regulations herein.

Purpose or Scope of the Legislation

There is no "purpose" provision in the preamble of the Notification Regulations. Despite the fact that the legislation was promulgated by the Ministry for Labour, the legislation is not oriented toward occupational health and safety. The Notification Regulations are no more comprehensive than necessary to implement the Sixth Amendment.

Effective Date of Notification Requirement

The Notification Regulations came into operation on September 1, 1982 (7).

Type of Notification

Substances "shall not be placed on the market" unless notification has been made to the competent authority (8). The regulations have a minimal definition section. Rather, the definitions in the Sixth Amendment are adopted by reference (9). Thus, according to the

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(5) Section 3 of the Act, No. 27 of 1972.

(6) Statutory Instrument No. 258 of 1982. A complete text may be found in (Reference) Int'l Env. Rep. 251 : 5501-5505 (1983).

(7) Section 1, Notification Regulations. The regulations themselves were made July 30, 1982.

(8) Subsection 5(1).

(9) Subsection 2(2).

EEC Directive implementing the Sixth Amendment, "placing on the market" means supplying or making available to third parties, with importation being deemed to be "placing on the market" (10). Thus, the Irish system can be said to be a pre-marketing and pre-importing notification scheme.

Notification Time Period

Notification is to be made to the competent authority no later than 45 days before the substance is placed on the market (11).

Responsibility for Notification

"Manufacturers" or "importers" of a notifiable substance are required to submit the notification material (12). These two terms are not defined in the Notification Regulations or the Directive.

Notification Authority

The Notification Regulations refer to the competent authority without designating the specific entity to which notification of substances must be given. The explanatory note to the Regulations states that the Hazardous Substances Assessment Unit of the Department of Labour is the competent authority (13).

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(10) Council Directive 79/831/EEC, Article 2, para. 1, item (e).

(11) Subsection 6(1).

(12) Ibid.

(13) Also stated in European Community Information Service (1982).

Chemicals to be Notified

The Notification Regulations does not apply to (14):

- medicinal products;
- narcotics;
- radioactive substances;
- carriage of dangerous substances;
- foodstuffs or feedingstuffs;
- waste substances;
- substances in transit under customs supervision (provided they do not undergo treatment);
- pesticides and fertilizers (insofar as they are subject to similar approval procedures);
- substances already subject to notification requirements under other EEC Directives.

The legislation applies to substances and preparations, both of which terms have the definitions given in the EEC Directive, as they are not specifically defined in the Notification Regulations.

"New substances" are not specifically referred to in the regulations. However, notification is not required for substances on the EEC inventory which have been placed on the market before September 18, 1981 (15).

Total Exemptions

Notification is not required of the following:

(a) EEC exemption - there ought to be such an exemption in the Irish legislation, but it is not clearly stated as such. There is a vague phrase to the effect that notification is not required for "substances which are already subject to similar testing and notification requirements under existing Directives" (16).

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(14) Section 3.

(15) Subsection 3(3).

(b) Polymer exemption - if the substance is a polymer, polycondensate or polyadduct, except those containing in combined form 2% or more of any monomer unmarketed before September 18, 1981 (17).

(c) Testing exemption - if the substance is for research and analysis purposes and is placed on the market for determining its properties in accordance with the Directive (18).

(d) Research exemption - if the substance is placed on the market for research or analysis purposes in quantities of less than one tonne per year per manufacture or importer and intended solely for laboratories (19).

Partial Exemptions

(a) Quantity exemption - if the substance is placed on the market in a quantity less than one tonne per year per manufacturer (20).

However, in this case, the manufacturer must submit to the competent authority the identity of the substance, labelling data and quantity and must comply with any conditions imposed by the competent authority.

(b) Partial research exemption - if the substance is placed on the market for the purpose of research and development and if the quantity is greater than one tonne per year per manufacturer, then notification is not required for a period of one year.

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(16) Subsection 3(3)(c).

(17) Subsection 6(1) in reference to Article 8.1 of the Directive.

(18) Ibid.

(19) Ibid.

(20) Ibid.

In this case, quantities must be no more than necessary for research and development and the substance must be supplied to a "limited number of registered customers" (21). The manufacturer must submit the following information:

(i) identity of the substance;
(ii) labelling data;
(iii) quantity;
(iv) assurances that the substance will not be available to the public.

The manufacturers must comply with any conditions imposed by the Minister for Labour on the research and development.

(c) Ten year exemption - if the substance was originally notified at least 10 years previously then the notifier need not include in the technical dossier the information required by Annex VII (22) except for information on the identity of the substance, proposed uses and production/imports and recommended precautions.

Inventory

The Notification Regulations rely on the EEC inventory of substances on the market in the EEC before September 18, 1981 in order to distinguish between "new" substances requiring notification and "old" substances which don't (23).

Annex I of the Sixth Amendment is adopted by reference. This annex lists dangerous substance. If a substance is in that inventory some information, otherwise required to be notified, may be dispensed with (24).

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(21) Subsection 8(5) - "registered" with whom?

(22) of the Directive.

(23) Subsection 3(3).

(24) Subsection 6(3).

Content of Notification

The notification system requires that the following be submitted to the competent authority (25):

(a) technical dossier - supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment,

containing at least the information and results of the studies referred to in Annex VII, together with a detailed and full description of the studies conducted and of the methods used or a bibliographic reference to them;

(b) if required, a summary of the technical dossier information necessary for evaluating the foreseeable risks;

(c) a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged;

(d) the proposed classification and labelling;

(e) proposed recommendations relating to the safe use of the substance.

Testing Requirements

As mentioned above, the technical dossier must contain the results of the tests set out in Annex VII, the "base set" of tests. Further tests may be required as discussed, infra.

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(25) Subsection 6(1).

Mutual Acceptance of Data

The Irish legislation seems to have been copied from the Sixth Amendment without sufficient adaptation as national legislation. The standard EEC exemption, as discussed supra is not clearly set out. Nor is the related concept of "mutual acceptance of data".

If "notification" is as defined in the Directive (it not being defined in the Irish legislation) then impliedly there is mutual acceptance of data - notification elsewhere in the EEC is notification sufficient for Ireland. In the confidentiality provision of the Notification Regulations, the transmittal of notification material is implied.

Flexibility in Notification Requirements

Other than the exemptions noted above there does not appear to be provision for the omission or substitution of the basic information to be supplied.

Unlike the legislation of other EEC Member States, the Notification Regulations do not clearly set out the further requirements if quantities reach certain levels such as 10/50, 100/500, 1000/5000 tonnes per manufacturer or importer or cumulative. Instead, the legislation states that a notifier shall inform the competent authority of "the results of studies carried out in accordance with Annex VIII" (26). The Annex VIII tests were designed to be applied in a flexible manner. The Level One tests, where quantities reach 10/50 tonne levels may be required, and they shall be required (unless alternatives would be preferable) if 100/500 tonne levels are reached. When 1000/5000 tonne levels are reached, a "programme of tests" will be set up which shall (unless there are strong reasons to the contrary) include the Level Two tests.

There is a further provision that the Irish competent authority may, if it is necessary, ask for the Annex VIII test results "earlier than provided for therein" (27). But this does not solve the problem of when and with what flexibility will the Annex VIII tests be required in the first instance. Will a notifier automatically do the Level One tests if quantities reach 10/50 tonne levels, or will a notifier automatically submit the tests results if the notifier happens to do the Level One tests if requested (because Annex VIII does say "may")?

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(26) Subsection 6(4).

(27) Subsection 7(1).

As mentioned above, some information may be deleted if the substance is in the Annex I dangerous substance list.

If the substances which are covered by the polymer, testing, research, quantity and partial research exemptions discussed supra are "very toxic" or "toxic", the manufacturer or importer shall provide information regarding handling precautions, etc. and emergency measures (28).

Further Testing/Follow-up Measures

As mentioned, there is some confusion about the circumstances under which Annex VIII tests will be done. But as noted, the Annex VIII tests may be required earlier than provided for if it is necessary.

The notifier of a substance already notified shall inform the competent authority of (29):

(a) changes in quantities per year, or accumulated quantities, placed on the market at the following levels: 1, 10, 50, 100, 500, 1000 and 5000 tonnes;

(b) new knowledge of the effects of the substance on man or the environment (or both) of which the notifier may reasonably be expected to have become aware;

(c) similarly, new uses;

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(28) Subsection 8(4).

(29) Subsection 6(4).

(d) any changes in the properties relating to the composition of the substance;

(e) as discussed in the previous section, supra, the results of the tests in Annex VIII.

Special Orders

If it can be shown (by whom?) to be necessary for the evaluation of the hazard which may be caused by a substance, the competent authority may ask for further information and/or verification tests. It may also carry out sampling as necessary for control purposes. The competent authority may "take appropriate measures relating to the safe use of a substance pending the introduction of Community provisions" (30).

If the competent authority has evidence that a substance constitutes a hazard by reason of its classification, packaging or labelling, even though the requirements of the Directive and the Regulations are otherwise satisfied, then the Minister of Labour may "provisionally prohibit" the sale of the substance, or may subject it to special conditions (31).

Protection of Confidential Data

A notifier may indicate information required to be submitted on the initial notification which the notifier considers to be commercially sensitive, but must give justification (32). "Industrial and commercial secrecy" shall not apply to (33):

(a) the trade name of the substance;
(b) physico-chemical data;

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(30) Subsection 7(1).

(31) Section 18.

(32) Subsection 9(1).

(33) Subsection 9(2).

(c) the possible ways of rendering the substance harmless;
(d) the interpretation of the toxicological and ecotoxicological tests;
(e) the name of the entity doing the above tests;
(f) recommended precautions and emergency measures.

The competent authority has the last word as to what is to be confidential (34), but once classified as confidential, the competent authority must keep it secret (35) except with respect to the following (36):

(a) the EEC Commission;
(b) the competent authorities of the EEC Member States (37);
(c) administrative or legal proceedings involving sanctions (but the data may be disclosed only to persons directly involved in the proceedings) (38).

If the notifier discloses data which has been classified confidential then the competent authority shall be informed (39).

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(34) Subsection 9(4).

(35) Subsection 9(5).

(36) Subsection 9(6), 9(1).

(37) But the provision does not make the provision of confidential data to other competent authorities conditional on the existence of similar confidentiality mechanisms in other countries.

(38) Judges generally have control over the proceedings in their own courts. What if a judge decides that the public interest is best served by full disclosure to the media?

(39) Subsection 9(3). Does this mean that the competent authority may then disclose the information? The provision doesn't state "public disclosure". What if the notifier discloses data to a select group but not to the public (or competitors) - does this provision imply that the notifier has waived its rights to confidentiality?

Disclosure of Data and Proprietary Rights

If a substance has already been notified the competent authority may agree that a subsequent notifier of that substance may refer to the results of studies conducted by previous notifiers, for the purposes of the technical dossier. However, the previous notifiers must give their consent in writing (40). This, presumably, will allow commercial arrangements to be made between chemical companies for the sharing of data.

Public Participation

There does not appear to be provisions in the Notification Regulations for general public disclosure of information or for public participation in the decision-making process.

Enforcement and Penalties

A person who contravenes any of the notification provisions is guilty of an offense and on summary conviction is liable to a fine not to exceed £ 600 (41). There is a one year limitation period (42).

It has been pointed out supra how it came to be that the penalty is limited to such as low a sum as £ 600 and without possibility of a jail term. Other Member States of the EEC have much higher penalties.

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(40) Subsection 6(2).

(41) Subsection 15(1).

(42) Subsection 15(3). In other words, prosecution must begin within one year of the date on which the offence was committed. If a large quantity of a particularly hazardous substance is imported into Ireland in one shipment and two years later it is discovered that notification was not given and in the meanwhile great environmental damage was done, the perpetrator cannot be charged. Perhaps the provision should have phrased the limitation period as one year from the date on which the offence became known to, or ought reasonably to have become known to, the competent authority.

2.7 ITALY

Italy is a Republic with a written constitution. The latter establishes the Central Government, with its attendant Ministries, and three levels of more local jurisdiction: regional, provincial and commune. Italy has a President, a Prime Minister who heads the executive and a two chamber Parliament. Parliament is the supreme legislative authority although the regional authorities have some autonomous powers of legislation (1).

Generally, Italy has lagged behind other industrialized nations in the area of environmental law. When most developed countries were enacting a wide variety of environmental legislation during the 1970s, Italy, a country with virtually no energy resources of its own, was enduring severe economic hardship in the aftermuth of the 1973 oil crisis - environmental issues were not a priority (2).

No single Ministry is totally responsible for environmental matters. The Ministry of Health is charged with responsibility for public health and is the coordinating entity for delegated powers regarding public health.

Overview

Italy has implemented the EEC Sixth Amendment through the issuance of Presidential Decree No. 927 in 1981 (3). Decree No. 927 amended Law No. 256 of 1974 (4) in a rather peculiar way. Numerous minor amendments were made with respect to classification, packaging and labelling matters. The Decree amended Article 2 of Law No. 256 to provide a general provision requiring notification but the details of the notification scheme are contained in Decree No. 927 itself. A Circular was subsequently issued in 1982 pursuant to Decree No. 927 which provided further details of notification procedures (5).

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(1) McLoughlin and Forster (1982).

(2) (Reference) Int'l Env. Rep. 261 : 0101 (1978).

(3) Presidential Decree No. 927 of November 24, 1981, Gazzetta Ufficiale della Repubblica Italiana, Part I, February 20, 1982, No. 50, pp. 1280-1293. An edited version appears in IRPTC Bull. 5 : 34-35 (1983); it is noted in Int'l Dig. of Health Leg. 34 : 623-624 (1983).

(4) Law No. 256 of May 29, 1974. This Law concerns the classification, packaging and labelling of dangerous substances and preparations (Springborn, 1982). Despite an apparent poor record with respect to environmental law, such a law, enacted during the 1970s, might be expected given that the chemical industry is a significant sector of the Italian economy. Chemicals amounted to 7% of Italy's exports in 1981 -Encyc. Brit. (1983).

The Ministry of Health is responsible for the supervision of Italy's notification system but relies on a Consultant Commission in the evaluation process. This Commission has representatives from a number of other Ministries. Such interministerial commissions appear to be utilized in Italy for a variety of environmental matters.

Decree No. 927 follows the wording of the Sixth Amendment closely. Annex I and Annex II to the Decree appear to be equivalent to Annex VII and Annex VIII but an English copy of the Annexes is not readily available (6).

Status of Implementation

As mentioned, Decree No. 927, issued in 1981, contains Italy's notification system pursuant to the Sixth Amendment.

Purpose or Scope of the Legislation

There is no express provision in Decree No. 927 setting out the purpose or scope of the legislation. Perhaps such provision appears in Law No. 256.

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(5) Circular No. 21 of March 24, 1982, Gazzetta Ufficiale della Repubblica Italiana, Part I, April 1, 1982, Ordinary Supplementary to No. 90, pp. 1-142.

(6) In fact, the English translation of Decree No. 927 is very poor. Many terms have clearly not been precisely translated.

Effective Date of Notification Requirement

Decree No. 927 was issued November 24, 1981, two months after the required implementation date of September 18, 1981. There is no provision in the Decree postponing its application, therefore the effective date of notification is either November 24, 1981 or February 20, 1982, its official publication date (7).

Type of Notification

Notification must be given by the manufacturer or any other person who introduces the substance, or a product prepared with the substance, to the market. Importing into Italy is "introducing to the market" (8). Therefore, the system requires pre-marketing and pre-importing notification. "Introduction to the market" means "delivery or disposal to others" (9).

Notification Time Period

Notification is required 45 days before a substance is introduced to the market or imported (10).

Responsibility for Notification

Manufacturers or importers are responsible for notification (11). Neither term is defined in the Decree although either or both may be defined in Law No. 256.

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(7) See footnote (3).

(8) Article 6 - Decree.

(9) Ibid.

(10) Ibid.

(11) Ibid.

Notification Authority

The Ministry of Health is responsible for the notification system. The Health Department of the Food and Drug Administration has several duties in the Decree, but it is not clear if the Food and Drug Administration itself is under the Ministry of Health. While the Ministry of Health receives notification material, evaluation is done by a Consultant Commission drawn from a number of government agencies (12).

Chemicals to be Notified

Law No. 256 was amended by the Decree so that the following are not covered by the legislation as there are other regulations in effect (13):

(a) medicines and drugs;
(b) radioactive substances;
(c) transportation of dangerous substances;
(d) food or animal feeds;
(e) "substances that have residual forms, including among them such substances in which the container dissolves by itself" (14);
(f) substances in transit, under customs control, if they are not processed;
(g) compressed or liquified gas or gas dissolved under pressure (15);
(h) explosives marketed as such (16);

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(12) Articles 10 and 11 - Decree.

(13) Article 1 - Decree.

(14) It is not clear what this means.

(15) Article 5 - Decree.

(16) Ibid.

(i) to anti-parasitical (17) substances or organic fertilizers provided it is in conformity with other EEC notification procedures (18);

(j) substances subject to other EEC procedures involving testing and notification (19);

Products themselves do not appear to be notifiable items, but an otherwise notifiable substance in a product must still be notified (20).

Decree No. 927 does not define "substance", but it may be defined in Law No. 256.

The notification system applies to "new" substances not marketed before September 18, 1981. However, six months after the EEC inventory is published, notification will be required for substances not on the inventory (21).

Total Exemptions

Notification is not required of the following:

(a) EEC exemption - if the substance has already been notified in an EEC Member State (22).

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(17) Veterinary medicine?

(18) Article 8 - Decree.

(19) Ibid.

(20) Article 6 - Decree.

(21) Article 8 - Decree.

(22) Article 8 - Decree; this provision refers to Regulation No. 831 of September 18, 1979, but it is not clear what this is or what its connection with previous notification is. The Regulation is not readily available.

(b) Polymer exemption - if the substance is a compound of polymerization, polycondensation or polyaddition with less than 2% of a monomer in bound form which has not been commercialized before September 18, 1981 (23).

(c) Testing exemption - if the substance is introduced to the market for research and analysis to determine its properties in conformity with the Decree (24).

(d) Research exemption - if the substance is introduced to the market for research and analysis, in a quantity less than one tonne per year per manufacturer or importer, and the substance is destined solely for laboratories (25).

If the substance is "very toxic" or "toxic" in (b)-(d) *supra*, then information in points 2.3, 2.4 and 2.5 of Annex I of the Decree must be notified (26).

Partial Exemptions

Some substances are subject to limited notifiction requirements:

(a) Quantity exemption - if the substance is introduced to the market in a quantity less than one tonne per year per manufacturer or importer, if the identity, labelling data and quantity are notified and if "rulings" of the Ministry are complied with (27).

(b) Partial research exemption - if the substance is introduced to the market in limited quantity for the purpose of research and development, but in excess of one tonne per year per manufacturer or importer and if there are a limited number of registered clients, then the substance is exempt for one year. The same data as in (a) supra must be notified (28).

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(23) Article 8 - Decree.

(24) Ibid.

(25) Ibid.

(26) This presumably is the information relating to recommendations for safe use, etc.

(27) Article 8 - Decree.

(c) Ten year exemption - If the substance was first notified at least ten years in the past, then the notifier is not required to submit the Annex I (Annex VII equivalent) data, except for some minimal identity data (29).

Inventory

Decree No. 927 refers to a substance list in Annex I of Ministerial Decree of December 17, 1977 (30). As Decree No. 927 does not have a list of "dangerous substances" as many Member State implementing legislation does, the Annex I list of 1977 is probably such a list.

There is no other indication of an Italian effort to inventory substances. The notification system will depend on the EEC EINECS inventory.

Content of Notification

The notification material must include (31):

(a) technical data supplying all the necessary elements to evaluate. Such data must have all the data and results of all the studies set out in Annex I, detailed descriptions of the studies, and methods and their bibliographical references;

(b) declaration regarding the negative effects relative to the foreseen uses;

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(28) Ibid.

(29) Article 6 - Decree.

(30) Ibid. The 1977 Decree is not readily available.

(31) Article 6 - Decree.

(c) proposed classification and labelling in accordance with Law. No. 256.

(d) proposed recommendations concerning the safe use of the substance.

Testing Requirements

The results of the tests in Annex I, which appears to be similar to Annex VII of the Sixth Amendment, must be provided. The translation of Decree No. 927 is not clear but it appears that tests must be performed at laboratories authorized by the Ministry of Health.

Additional tests set out in Annex II of the Decree may be required as noted infra.

Mutual Acceptance of Data

The Decree provides that notification is not required if the substance has been notified in another EEC Member State (32). Provision is also made for the transmission of notified material to the EEC Commission. The Ministry of Health can add its own comments to the material. If further tests are required of a notifier, the results as well as the rationale for requesting the tests will also be transmitted. The material can be transmitted in resume form. If requested, the Ministry of Health will transmit material to the competent authorities of other Member States (33).

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(32) Article 8 - Decree; see footnote (22).

(33) Article 7 - Decree. The provision does not state that transmission is contingent on other Member States having implementation procedures in effect; particularly regarding confidentiality.

Flexibility in Notification Requirements

There is a vague provision in the Decree, which undoubtedly suffers from poor translation, which seems to indicate that if a substance is a "dangerous substance" then some data may be dispensed with (34).

A notifier must inform the competent authority of changes in the quantity of substance introduced to the market (35). The competent authority may request additional information or tests as per Annex II to the Decree, which appears to be equivalent to Annex VIII of the Sixth Amendment (36). The 10/50, 100/500, 1000/5000 tonne levels which trigger Annex VIII are not expressly stated in the Decree. Annex II is not translated in the readily available English version of the Decree but presumably the levels are stated in Annex II. If the Annex II wording follows that of Annex VIII then there is flexibility in the number and type of tests to be required when the quantity levels are reached.

Further Testing/Follow-up Measures

Other than changes in the quantity of substance introduced to the market every year, a notifier is required to report (37):

(a) new knowledge regarding the effects of the substance on health and the environment;

(b) new uses;

(c) changes in properties resulting from changes in composition.

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(34) Article 6 - Decree. The provision refers to a substance already recorded in Annex I of a Ministerial Decree of December 17, 1977.

(35) Article 6 - Decree.

(36) Article 7 - Decree.

(37) Article 6 - Decree.

If the Ministry of Health deems it necessary in order to evaluate the danger a substance can present, it has authority to (38):

(a) request the additional information and tests set out in Annex II (39);

(b) take samples;

(c) take "necessary steps relative to safe usage" pending EEC regulations.

Special Orders

Other than the follow-up measures noted supra, there is no provision in the Decree for special orders. It is not known if there are such provisions in Law No. 256.

Protection of Confidential Data

If disclosure of submitted data could harm a notifier industrially or commercially, he may request that such information be kept secret from any person who is not (40):

(a) involved in the Italian notification system, including the Consultant Commission;
(b) the EEC Commission; or
(c) the competent authorities of other EEC Member States.

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(38) Article 7 - Decree.

(39) The provision does not state that the competent authority can ask for the Annex II tests before the specified quantities marketed are reached.

(40) Article 9 Decree.

Justification for a request for secrecy must be provided. If the notifier divulges the confidential data himself, he must inform the Ministry of Health. The Decree also provides that if the substance is not classified as "dangerous" its identity can be encoded in the EEC inventory, but for no more than three years (41).

Some information may not be considered confidential (42):

(a) the commercial name of the substance;
(b) the physico-chemical data of the substance as in point 3 of the Annex I of the Decree;
(c) ways of neutralizing the substance;
(d) interpretation of toxicological and ecotoxicological tests and the name of the party performing the tests;
(e) precautionary and emergency measures in Annex I.

Disclosure of Data and Proprietary Rights

Data may be disclosed to the EEC Commission and the competent authorities of other Member States as noted, supra.

The Decree provides that if a substance has been previously notified the "Health Department (Food and Drug Administration) can accept the notification of past technical data and the results of past studies" (43). This provision may suffer from poor translation as the Ministry of Health supervises the notification system. Second, is it only the information used or the actual "notification" of previous notifiers? There is no requirement that the previous notifier must agree in writing to the use of its data. The provision could mean that previous data can be used by the same notifier. It is unclear.

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(41) Ibid.

(42) Ibid.

(43) Article 6 Decree.

Public Participation

There is no provision for public participation in the Decree.

Enforcement and Penalties

The Decree does not contain enforcement or penalty provisions. They are likely contained in the parent Act, Law No. 256, which is not readily available.

2.8 LUXEMBOURG

The Grand Duchy of Luxembourg is a representative democracy in the form of a constitutional monarchy. The Grand Duke is the executive authority, assisted by a Cabinet. His government acts must be countersigned by a competent Cabinet minister. The legislative branch is comprised of the Grand Duke and the unicameral, elected Chamber of Deputies. No bill may be passed without mutual consent of the Grand Duke and the Chamber. Most bills are proposed in the Chamber by ministers. An independent judiciary administers a court system modelled on the French system. The population of the country is only 365,000. The country is divided into three districts, 12 cantons and 126 municipalities, but the country is not based on a federal system (1).

Luxembourg's Ministry of the Environment was created in 1980. The National Committee of the Environment was formed in 1981. It is multidisciplinary advisory group which consists of various government ministers and is led by the acting President of the Government (2).

The first step toward modern chemical control legislation came in 1979 when a law was passed concerning the classification, packaging and labelling of dangerous substances (3). This was followed by Ministerial Regulations of 1982 which established an Interministerial Committee to examine notification dossiers in accordance with the Sixth Amendment. The Committee is also charged with the responsibility of ensuring close collaboration with the competent authorities of other EEC Member States (4).

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(1) McLoughlin and Forster (1982) and (Reference) Int'l Env. Rep. 271 : 0101-0102 (1983).

(2) (Reference) Int'l Env. Rep. 271 : 0101-0102 (1983).

(3) Law of March 14, 1979 On the Classification, Packaging and Labelling of Dangerous Substances, Memorial: Journal Officiel du Grand-Duche de Luxembourg, Part A, March 23, 1979, No. 22, pp. 424-428 (corrigendum, ibid, May 29, 1979, No. 43, p. 914); noted in Int'l Dig. of Health Leg. 31 : 80-81 (1980).

(4) Ministerial Regulations of October 22, 1982 On the Establishment of an Interministerial Committee, Memorial: Journal Officiel du Grand-Duche [illegible] Luxembourg, Part A, November 12, 1982, No. 94, pp. 1940-1941; an exerpt appearing in Int'l Dig. of Health Leg. 34 : 319-320 (1983).

A Bill has been drafted which, when enacted, will implement the notification requirements of the Sixth Amendment. It is not certain at this time whether a final Act has been passed. It follows that it is also not known if substantial changes have been made to the Bill. While there is no indication in the international literature that the Bill has been passed into law, there have been several news reports that indicate that Greece is the only EEC Member State which has not implemented the Sixth Amendment.

The English version of the draft Luxembourg Bill is a crude translation. However, three points may be made. First, the Bill represents a complete notification system in itself. Second, the wording appears to track the form and substance of the Sixth Amendment almost verbatim. Third, there are three areas in which the Bill departs from the wording of the Sixth Amendment and these relate to the competent authority, importation, and enforcement and penalties.

Since it is a draft Bill and not a final Act, and since it is virtually identical to the Sixth Amendment, only the three areas in which the Bill departs from the Sixth Amendment will be reviewed here.

Notification Authority

The Bill provides that the competent authority which will evaluate submitted material will be composed of three entities: the Labour Institute, the National Laboratory of Health and the Environment Administration (5). Each of these will evaluate material according to their area of competence. That these three government bodies comprise the competent authority reflects the fact that there are three Ministries which have had the responsibility of implementing the Sixth Amendment: Public Health, Environment and Labour (6).

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(5) Article 7, para. 1 - Bill.

(6) Springborn (1982); The European Community Information Service (1982) refers to the Environment Administration alone as the competent authority.

The Bill provides that a committee will be established by regulation and that notification material is to be sent to the President of the committee. This has already been done by the regulation, noted supra, of 1982 (7).

Importation

The Bill follows the Sixth Amendment in every reference to importing substances except for one provision (8). This states that every importer of a dangerous substance must be in possession of a certificate from the government of the exporting country certifying that the dangerous substance conforms with the exporter's national legislation. This provision does not apply to other Member States of the EEC.

It is not indicated in the Bill whether the certificate must be notified to the competent authority. Presumably the importer must present the certificate to some government body at some time; possibly the customs authorities. This is a good example of a non-tariff trade barrier. Does the Canadian government provide Canadian exporters to Luxembourg with such a certificate?

Enforcement and Penalties

The Sixth Amendment does not contain enforcement and penalty provisions. These are left to Member States. The Luxembourg Bill provides that the police, as well as experts and agents to be designated by regulation, will enforce the law when passed (9). These enforcement personnel have search and seizure powers as well as the authority to take samples for analysis (10).

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(7) This fact in itself suggests that the Bill was passed some time ago, unless the regulation was issued pursuant to some other law.

(8) Article 19 - Bill.

(9) Article 22 - Bill.

(10) Articles 23 and 24 - Bill.

Violations may be faced with fines ranging from 25,000 to 250,000 francs and/or imprisonment from 8 days to one month. Criminal liability is contemplated. The Courts have the power to confiscate substances involved in a violation. If a second offence occurs within 2 years of a first conviction, fines may be increased up to 500,000 francs (11).

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(11) Article 25 - Bill.

2.9 NETHERLANDS

The Netherlands is a decentralized unitary state. It is a parliamentary democracy with a limited monarchy. Parliament (States-General) is a two-chambered body. There is a separation of legislative, executive and judicial powers. Executive power is exercised by Ministers on behalf of the Crown and they are responsible to the States-General for the exercise of that power (1).

The political and legal structure of the Netherlands is characterized by decentralized or delegated powers and extensive public participation. In fact, public participation is built into nearly every environmental law. Where consultation is not specified in a statute, the administrative agency concerned arranges for it as a matter of practice (2).

The Ministry of Health and Environmental Protection was established in 1971 and disbanded in late 1982. The environmental functions of the former ministry were absorbed by the Ministry of Housing and Physical Planning and public health matters were taken up by the Ministry of Welfare (3). This is of some importance as the implementation of the Sixth Amendment was under the jurisdiction of the former ministry and it was responsible for preparing the interim notification scheme as well as drafting the Bill discussed infra.

In 1983 and 1982 Canada exported $185 and 204.8 million in organic chemicals to the Netherlands (4).

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(1) (Reference) Int'l Env. Rep. 281 : 0101 (1980) and McLoughlin and Forster (1982).

(2) (Reference) Int'l Env. Rep. 281 : 0101 (1980).

(3) "New Cabinet scraps environment ministry transfers functions to other departments", (Current) Int'l Env. Rep. 5 : 482-483 (1982).

(4) "Canada - Netherlands trade", Toronto Globe and Mail, May 28, 1984, p. IB15.

Overview

The situation in the Netherlands is somewhat confusing. In 1981 a relatively simple instrument titled "Interim Decree on the Notification of New Chemical Substances" was issued (5). This was a voluntary system.

The Law of Environmentally Dangerous Compounds, which is to be cited as the Chemical Substances Act (6) was introduced as a bill in the 1980/81 parliamentary session (7). There is no indication in the international literature whether this bill was ever passed.

The Bill is comprehensive, being composed of 10 chapters and 78 sections. Although the Bill was introduced by the Ministry of Health and Environmental Protection, one source (8) has indicated that the Ministry of Public Health will have supervision. This is likely the result of the ministry shuffle noted *supra*. This Bill is intended to implement the Sixth Amendment and is concerned primarily with the environment and with public health and safety.

Apparently, there will be a second law implementing the Sixth Amendment. This will deal with the safety of the working population and will be under the responsibility of the Ministry of Social Affairs. Apparently the Ministry had not completed drafting the law in 1982 (9). There is no indication in the international literature that this law has been introduced as a bill let alone enacted. A copy therefore is not readily available for review.

Given the uncertain state of Netherland legislation, particularly in that it is not known to what extent the draft Chemical Substances Act will be modified before being passed, this review will briefly examine the interim scheme and then point out some of the more important features of the Bill.

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(5) Interim Decree on the Notification of New Chemical Substances of September 7, 1981, Nederlandse Staatscourant, September 11, 1981, No. 174, p. 7. Published in condensed form in IRPTC Bull. 5 : 32-33 (1982) and noted in Int'l Dig. of Health Leg. 34 : 624 (1983).

(6) Section 77 - Bill.

(7) No. 16,800.

(8) Springborn (1982).

(9) Ibid.

Interim Decree

The Decree entered into force on September 18, 1981 (10) in time to meet the implementation requirement of the Sixth Amendment. There were no penalty or enforcement provisions attached. It appears to be a voluntary scheme without legal obligation. The notification authority is the Chemical Substances Bureau of the Ministry of Health and Environmental Protection (11), although what became of the Bureau after the demise of the latter ministry is not known.

The Decree adopts by reference various articles of the Sixth Amendment. Notifications as referred to in Article 6, para. 1 of the Sixth Amendment Directive, supplementary notifications as referred to in Article 6, para. 4 and the results of the studies as referred to in Article 6, para. 5 may be submitted to the Bureau (12).

There are several interesting points. Descriptions of the studies and their results may be submitted in Dutch, French, German or English (13). If the Bureau is not satisfied with the notification material it shall inform the notifier within 30 days of receipt (14). Similarly, the Bureau is required to inform the notifier within 30 days of receipt as to its decision whether a request of confidentiality is justified (15).

Unlike other European nations, and similar to the U.S. TSCA, the Decree provides that notifications will be published in the Government Gazette and the public may inspect the material and obtain a copy. Confidential material is not included in this provision (16).

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(10) Article 10 - Decree.

(11) Articles 1 and 2 - Decree.

(12) Article 2, para. 2 - Decree.

(13) Article 2, para. 5 - Decree.

(14) Article 3, para. 2 - Decree.

(15) Article 5, para. 2 - Decree.

(16) Article 6 - Decree.

There is provision that the Bureau will transmit notification material to the EEC Commission, but there is no mention of forwarding material to other Member States (17).

The Interim Decree serves two purposes: 1) to fulfill the Netherland's responsibility with respect to meeting the September 18, 1981 deadline; and 2) to serve as a pilot project for the final system.

To what extent does the interim system foreshadow the final system?

Chemical Substance Bill

The following are the more significant or interesting characteristics of the Chemical Substance Bill:

(a) The term "substance" does not include foodstuffs, stimulants, tobacco or animal feeding stuffs. However, in the latter part of the Bill it is stated that the legislation does not apply to medicines, pesticides, nuclear material, transportation of dangerous compounds and wastes covered by specified Acts (18).

(b) The system is a pre-manufacturing, pre-importing and pre-marketing notification scheme (19). It is not just a pre-marketing scheme although manufacturing is defined as producing a substance "in order to put it into circulation".

(c) The content of the notification is not set out in the Bill, other than by general category, but will be specified by General Administrative Order (20).

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(17) Article 8, paras. 2 and 4 - Decree.

(18) Sections 1 and 76 - Bill.

(19) Section 3 - Bill.

(20) Subsection 4(1) - Bill.

(d) The notification material does not specify that a technical dossier or a declaration will be submitted - just the data and test results, although this is a difference of form rather than substance.

(e) The notifier does not have to carry out tests if he is "able to obtain the required data in some other way" (21).

(f) If a substance contains impurities or additives the tests must be done on the substance together with such impurities or additives (22).

(g) An importer who is not an EEC resident must appoint a resident agent to represent him with respect to notification (23).

(h) The notifier is sent a receipt for the notification within one week of the competent authority receiving it (24).

(i) The competent authority must inform the notifier within 30 days if the notification is not satisfactory and must give reasons. The notification is then deemed not to have been given (25).

(j) In the case of pre-manufacturing (but not pre-importing or pre-marketing) notification, the 45 day period may be extended up to 5 months for certain substances if so designated by Order (26).

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(21) Subsection 4(3) - Bill.

(22) Subsection 4(4) - Bill.

(23) Subsection 4(5) - Bill.

(24) Subsection 6(1) - Bill.

(25) Subsections 7(1) and (2) - Bill.

(26) Subsection 8(3) - Bill.

(k) There are numerous provisions setting out when, in what manner, and with what information, the competent authority will publish and display notification material (27). The provisions are relatively unusual compared with the unstated secrecy by which the systems of other countries operate.

(l) Also unusual is the provision allowing the competent authority to accept written comments from the public on the disclosed information. The comments are also disclosed to the public and copies are sent to the notifier (28).

(m) The competent authority is obliged to issue a declaration to the notifier and the public indicating, with reasons, whether the known data or the public comments have caused him to consider measures or tests with respect to the substance (29).

(n) If the substance is for export outside the EEC, the publication, etc. of the notification material and the declaration need not be given (30).

(o) On substantiated grounds of confidentiality a notifer may request that the publication, etc. and declaration be dispensed with (31).

(p) The Annex VIII tests are not cited nor is a similar list of studies published. The step sequencing aspect of the Annex VIII tests with respect to the 100/500 and 1000/5000 tonne levels is set out but it is up to the competent authority to decide what the tests will be (32).

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(27) Sections 9, 10, 11, 12, 13 and 14 - Bill.

(28) Section 14 - Bill.

(29) Sections 15, 16 and 17 - Bill.

(30) Section 18 - Bill.

(31) Section 19 - Bill.

(32) Sections 22 and 23 - Bill.

(q) Notifiers are required to retain all data for at least 5 years after the conclusion of manufacturing or importing (33).

(r) If the notification is subject to publication, the substance will be recorded in a public register. Information similar to the Sixth Amendment list of non-confidential data is also included. The chemical name may be excluded from the register (34). Thus it appears that the Netherlands will be developing its own inventory - but of notified substances.

(s) The exemption provisions are worded very differently from the Sixth Amendment. Pre-September 18, 1981 substances and substances for laboratory research in quantities less than one tonne are exempt. A substance is exempt if it is not in "free" commerce in the Netherlands and it is not processed or converted in the Netherlands. Intermediates generally are exempt from notification (35).

(t) There are broad investigative powers which would include the power to require data to be submitted and tests done for dangerous substances, but the competent authority must act by Order (36).

(u) Despite the fact that the Bill is very comprehensive in itself, it is clear that it is meant to be an even more comprehensive "enabling Act" as there is an extensive list of matters which may be covered by regulation (37).

(v) There is provision for an eventual permit system as well as a "superfund" mechanism to collect levies to cover the cost of the administration of the Act (38).

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(33) Section 25 - Bill.

(34) Section 26 - Bill.

(35) Subsection 27(1) - Bill.

(36) Section 29 - Bill.

(37) Section 30 - Bill.

(38) Sections 30 and 32 - Bill.

(w) Manufacturers and importers (and potentially users) shall be required to keep a register of quantities of substances and preparations manufactured, imported or marketed (39).

(x) The Bill's notification provisions are accompanied by a labelling and packaging system (40).

(y) There are extensive enforcement powers of inspection, search and seizure (41).

Summary

Of all the legislative mechanisms adopted by EEC Member States to implement the Sixth Amendment, the Netherland's prospective legislation is the most complex, original and perhaps even the most uncertain. While some Member States have virtually copied the Sixth Amendment, the Dutch have combined the latter's requirements with numerous other objectives and concepts. It is difficult to identify many of the Sixth Amendment's provisions in the Bill. It is fair to say that the Netherlands has taken a different path towards chemical control and has done so in a manner that does not serve the EEC goal of harmonization of national legislation. Needless to say the Dutch chemical industry is not happy with the Bill. As one source has reported (42):

> The one-sided introduction of pre-manufacturing notifications in the Netherlands, covering also substances which are only exported to non-Member States, causes a rise in costs to the Dutch producers which is not experienced in other Member States, and which will especially be considerable for substances produced via one or more intermediates. This threat to the competitiveness of the Dutch producers is felt to be unnecessary as there are a sufficient number

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(39) Section 37 - Bill.

(40) Part 2 - Bill.

(41) Chapter 7 - Bill.

(42) Dieleman (1982).

of other legal instruments to protect man and the environment against the risks involved in the production of a new substance. The proposed levies to finance the administration of the law will further increase the costs to the industry.

The system of the Ministerial Declaration is felt to be a masked permit system. Although the placing on the market is not suspended by these declarations, and although they have no legal consequences, it is likely that notifiers will want to await the final declaration.

Experience with the administration of other environmental laws creates the fear that the six month delay in preparation of a final Ministerial Declaration will be exceeded. It is feared that the laying open of the data for public comment, in spite of confidentiality considerations, will create serious confidentiality problems and hinder the exchange of dossiers between the Member States.

Under the provisional proposal for the existing substances, the Minister enjoys extensive powers leading to uncertainty as to the handling procedures still be be established through administrative orders.

Because of the limited capacity of available toxicological laboratories and the complexity of the matter, the Dutch chemical industry has always taken the position that the problem of the existing substances should be tackled on an international basis.

The Dutch chemical industry has petitioned parliament with the above objections. In the case that the parliament would not move to the position of the industry, the parliament has been requested to implement the 6th Amendment first and that the extra provisons should be brought in gradually over a period of time so that the Dutch chemical industry would not immediately be subject to a large commercial disadvantage.

2.10 UNITED KINGDOM

Canada's constitutional, legal and political roots originate to a large extent in the United Kingdom. Perhaps the major differences are Canada's federal nature, its bilingual/bicultural status (which finds its closest European analogies in the cases of Belgium and Switzerland) and the fact that the United Kingdom is now part of the supra-national sovereign entity known as the EEC.

Trade in chemicals between Canada and the United Kingdom is relatively extensive. In 1983 Canada exported $98.0 million in chemicals to the U.K. and imported $85.7 million in chemicals from the U.K. (1).

Overview

The United Kingdom has implemented the Sixth Amendment by issuing regulations under an Act which predates the Sixth Amendment. That Act, the Health and Safety at Work Act 1974 (2) covers a number of topics but includes provisions "for controlling the keeping and use and preventing the unlawful acquisition, possession and use of dangerous substances" (3).

Section 6 of the Act requires that any manufacturer or importer of any "substance for use at work" must test the substance to see that it is safe to use, and poses no risk to health, and that adequate information be available regarding its safe use. There is a positive duty on the part of a manufacturer to arrange for research to be carried out in order that risks to safety or health be discovered. The manufacturer may rely on research conducted by others if it is reasonable to do so.

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(1) "Canadian-British Trade", Toronto Globe & Mail, May 28, 1984, p. IB14.

(2) Health and Safety at Work Act 1974, c.37. The relevant portions of the Act are reproduced in (Reference) Int'l Env. Rep. 291 : 8001-8005 (1979).

(3) Ibid., preamble to the Act.

This legislation was not designed specifically for a notification system. It is essentially occupational health and safety legislation. However, section 6 was presumably considered broad enough to permit the promulgation of regulations setting up a new chemicals notification system (4).

Although Northern Ireland is part of the United Kingdom, and is therefore subject to the EEC Directive, the legislation implementing the Sixth Amendment in the U.K. has expressly excluded Northern Ireland from its operation (except in regard to the importation of new substances from Northern Ireland into the rest of the U.K.). Northern Ireland introduces its own legislation in relation to the protection of man and the environment. Separate and complementary legislation will be introduced in Northern Ireland. Apparently the U.K. Health & Safety Executive will, by agreement, act as the competent authority for Northern Ireland (5).

Status of Implementation

The Sixth Amendment has been implemented by Notification of New Substances Regulations, 1982 (6). A guide to the Regulations has been published as well as codes of practice, approved by the U.K. Health and Safety Commission, for good laboratory practice, and for determination of physico-chemical properties, toxicity and ecotoxicity (7). The administrative machinery to accept notifications of new chemicals has been in place for several years (8).

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(4) A brief history of the implementation of the Sixth Amendment in the U.K. is given by Eberlein (1982). Authority for the implementation of the Sixth Amendment is more likely drawn from the European Communities Act 1972, c. 68; as noted in the preamble of the Health and Safety at Work Act 1974.

(5) Health and Safety Executive (1982).

(6) Statutory Instrument No. 1496, 1982. The Regulations have been reproduced (with Schedules) in (Reference) Int'l Env. Rep. 291 : 8221-8227 (1983). A digest of the Regulations may be found in Encyc. of Eur. Com. Law, Vol. AII, U.K. Sources, A3999:449-450.

(7) See citations in reference section infra, re: "Health and Safety".

(8) Springborn (1982), under United Kingdom.

Purpose or Scope of the Legislation

While the parent Act could be classified as occupational health and safety legislation, the Regulations are not; they are clearly and specifically designed to implement the Sixth Amendment. Their purpose is to protect man and the environment from risks associated with new chemicals.

Effective Date of Notification Requirement

The Regulations came into operation on November 26, 1982 (9). However, section 17 of the Regulations is a transitional provision which states that it would be sufficient compliance with the notification requirements (10) if manufacturers or importers informed the Health and Safety Executive of the date on which the new substance will be supplied (11) - provided that the notification requirements were eventually satisfied, no later than April 11, 1983. The latest date on which a new substance could be supplied under the transitional provision was 45 days later, May 26, 1983.

Type of Notification

Under the terminology of the Regulations, the type of notification required is "pre-supply". The term "supply" is defined in the Regulations to mean:

> "supply (whether as principal or agent for another) to any person in a member State by way of -

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(9) Section 1 of the Regulations.

(10) The requirements for the technical dossier, declaration, etc. set out in section 4(1).

(11) A defined term which includes marketing and importing, subsection 2(1) of the Regulations.

(a) sale, offer for sale, lease, hire or hire purchase; or
(b) commercial sample,
and includes importation into the United Kingdom." (12)

This definition of "supply" is broad, it includes marketing and importing. It would also seem to include exporting a new substance to another member State of the EEC.

Notification Time Period

A manufacturer or importer must comply with the notification requirements 45 days before the quantity of new substance supplied reaches a total quantity of one tonne or more in any 12 month period (13).

Responsibility for Notification

Manufacturers and importers must satisfy the notification requirements of subsection 4(1) of the Regulations. A "manufacturer" is defined as a person in a member State of the EEC who extracts, synthesizes or otherwise produces a new substance. An "importer" means a person who imports a new substance into the United Kingdom (whether or not that substance was consigned from the territory of a member State) (14).

Notification Authority

Subsection 4(1) of the Regulations requires that notification be sent to the "Executive", which is defined as the Health and Safety Executives (15). The Executive sends particulars of materials submitted to it to the Department of the Environment, but the latter does not appear to be a joint competent authority (16).

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(12) Ibid.

(13) Subsection 4(1).

(14) Subsection 2(1).

(15) See address of U.K. competent authority in European Community Information Service (1982).

Chemicals to be Notified

The Regulations refer to "substance", which is defined as an element or a compound, including "any additive required for the purpose of supplying the substance". Notification is required for a "new substance". A substance is "new" if it was not supplied to a person in a member state of the EEC at any time between January 1, 1971 and September 18, 1981 (17).

The Regulations do not apply to a new substance which is (18):

(a) medicine;
(b) a food additive;
(c) feeding stuff for agriculture;
(d) a radioactive substance;
(e) a pesticide (from a Member State if it is subject to appropriate approval procedure or in the U.K. if an exemption certificate has been obtained);
(f) a substance in transit under customs control which is not processed;
(g) a substance in a preparation if the substance by itself has already been notified (and by itself in quantity one tonne or more within 12 months).

Total Exemptions

Notification is not required of the following:

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(16) This, despite the fact that the Guide to the Regulations refers to both as the competent authority (p.v).

(17) Definitions are in subsection 2(1).

(18) Subsection 3(1).

(a) EEC exemption - if the new substance is imported from another Member State and it has been notified in accordance with the Sixth Amendment elsewhere (19).

(b) On-site exemption - if the new substance is not subject to an act of "supply", ie: used only in the establishment in which it is manufactured (20).

(c) Polymer exemption (21) - if the new substance is a polymer which contains less than 2% of a "new" monomer, and if the polymer is not "toxic" or "very toxic" (22).

(d) Testing exemption - if the new substance is supplied solely for the purpose of testing in order to comply with the Regulations, and if it is not "toxic" or "very toxic".

(e) Research exemption - if the new substance is supplied in a quantity of less than one tonne in any 12 month period for the purpose of laboratory research and if it is not "toxic" or "very toxic".

Partial Exemptions

Some substances are subject to limited notification procedures (23):

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(19) Subsection 4(2).

(20) This exemption is implied by the definition of "supply" and is referred to the Guide accompanying the Regulations (at p.4); see footnote (5) supra.

(21) Subsection 4(3) and Schedule 4 to the Regulations. The testing and research exemptions (d,e) are also found there.

(22) The criteria for classifying a substance as "toxic" or "very toxic" are given in Part II of Schedule 2 to the Regulations (which reproduces Part I of Annex VI to the Directive).

(23) Information supplied under the partial exemptions is not circulated among other EEC members as is the information (or at least a summary) supplied for full notification.

a) Commercial development exemption (24) - if the substance is for commercial development and if:

(i) the Executive is notified of the identity and quantity of the substance to be supplied and has been given recommendations for classification and labelling (25).

(ii) the Executive has been given a statement that an undertaking has been given that the substance is for commercial development only.

(iii) the substance has not been supplied for commercial development for more than one year.

(iv) if the substance is "toxic" or "very toxic", recommendations for safe handling and use must be provided to the Executive.

The Guide to the Regulations indicates that the purpose for this provision is that it will allow a manufacturer to provide a limited number of other companies to test the substance, along with others, to see which is the best prospect for full-scale marketing. Such substance can be tested for a one year period only.

(b) Quantity exemption (26) - if less than one tonne is supplied in 12 month period (other than research exemption) and if:

(i) the Executive is notified of the identity and quantity of the substance to be supplied and has been given recommendations for classification and handling.

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(24) Subsection 4(3) and Schedule 4.

(25) ie: the information required in para. 1 and para. 2.2 of Schedule 1 and subsection 4(1)(c). This also applies to the "quantity partial exemption".

(26) Subsection 4(3) and Schedule 4. The Guide to the Regulation (see footnote (5) supra) states at p.7 that the quantity relates to the Community market and not just to the U.K. market. This is a significant point, but it is not clear from the Regulations what the authority for this statement is.

(ii) if the substance is "toxic" or "very toxic", recommendations for safe handling and use must be provided to the Executive.

(c) Ten year exemption (27) - if previously notified at least 10 years before the date on which the manufacturer or importer intends to supply the substance (28) and if:

(i) the Executive is notified of the identity and general information on the substance (this includes recommendations for safe handling and use) (29).

Inventory

The EEC inventory system is not directly referred to in the Regulations. However, the definition of "new substance" requires that it be known whether a substance was supplied to a person in a Member State of the EEC between January 1, 1971 and September 18, 1981. The Guide to the Regulations does state, however, that when the EEC inventory is complete and published, the definition of "new substance" will have to be amended.

Content of Notification

Full notification requires:

a) a technical dossier (30);
b) a declaration concerning adverse effects;

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(27) Subsection 4(3) and Schedule 4.

(28) Obviously a number of years will have to pass before this partial exemption comes into operation. Note that there is no period after which a substance covered by the legislation escapes some notification requirements.

(29) Para. 1 and all of para. 2 of Schedule 1.

(30) Schedule 1 reproduces Annex VII to the Directive.

c) a declaration concerning whether the substance is "dangerous" (31). If it is, then particulars of its classification and (except for munitions and explosives) recommendations for labelling (32) must be given;

d) proposals for precautions for safe use of the substance.

Partial notification, as discussed under the heading "partial exemption", requires a portion of the information required for the technical dossier.

Testing Requirements

The technical dossier required by subsection 4(1) of the Regulations is to contain the results of the studies referred to in Schedule 1, which reproduces Annex VII to the Directive. A full description of the studies, the methods used or bibliographical references to them must be given. The 6 sections of Schedule 1 are:

a) Identity of the substance;
b) Information on the substance (eg: proposed uses and production/import);
c) Physico-chemical properties;
d) Toxicological studies;
e) Ecotoxicological studies;
f) Possibility of rendering the substance harmless.

As previously noted (33), the Health and Safety Commission has published four booklets containing approved codes of practice for good laboratory practice, and for methods for the determination of physico-chemical properties, toxicity and ecotoxicity.

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(31) Within the meaning of Part I of Schedule 2 (which reproduces Article 2(2) of the Directive).

(32) Schedule 2, Part I and Schedule 3 (which reproduces Article 16(2) of the Directive).

(33) See footnote (7).

Tests performed under the Regulations are to contorm to the principles of good current laboratory practice (34).

Mutual Acceptance of Data

Subsection 4(2) of the Regulations states that notification is not required if the substance is being imported from a Member State of the EEC and has been duly notified in accordance with the Directive elsewhere.

If the substance requires full notification then the Executive will send to the Commission of the European Communities a summary of the notification, further notification, results of further tests ordered and will respond to any proper requests for information from the CEC (35).

The Executive will send notification information to a competent authority in another Member State but the Executive is not obliged to do so if the other state does not have procedures in place for the protection of commercially sensitive information (36).

As noted previously, if a substance is subject to partial notification, the information will not be forwarded to the CEC.

Flexibility in Notification Requirements

The notification process is open-ended. Once a new substance has been notified, it is called a "notifiable substance" (37). The manufacturer or importer of a notifiable substance must notify the Executive of any material change in the intended uses for the substance or its properties as previously notified. Further, notice must be given of "any other information" which becomes available which might reasonably be expected to affect the interpretation of any information previously provided (38).

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(34) Section 11.

(35) Subsection 9(1).

(36) Subsection 9(3).

(37) Subsection 2(1).

Changes in the quantity supplied are deemed to be significant. The manufacturer or supplier must notify the Executive if quantities reach 10, 100 or 1000 tonnes in any 12 month period or a total of 50, 500 or 5000 tonnes, respectively (39).

Further Testing/Follow-up Measures

The Executive may require a manufacturer or importer of "notifiable substance" to carry out further tests and to report the results (40).

When the quantities supplied reach 100 or 1000 tonnes in any 12 month period, or a total of 500 or 5000 tonnes, respectively, the Executive must consider the need for further testing. In doing so, the provisions of Schedule 5 must be considered (41).

There are some constraints on the Executive's power to freely require further testing. The tests must be "reasonably required" for the evaluation of risks. To determine if they are reasonably required a number of circumstances must be considered such as quantity supplied, intended use, cost of testing, time required to carry out the tests, etc. (42). The Executive does not have to consider those circumstances if it is acting under a direction from the Secretary of State or a decision of the CEC (43).

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(38) Subsection 5(1).

(39) Subsection 5(2).

(40) Subsection 6(1).

(41) Schedule 5 reproduces the requirements of Annex VIII to the Directive.

(42) Subsection 6(3).

(43) Ibid.

Special Orders

Other than the powers set out above, further special powers are not evident.

Protection of Confidential Data

Information notified to the Executive is treated as confidential information under the Health and Safety at Work Act 1974, section 28 (44). It is classified "Commercial-in-Confidence" and standard government procedures to safeguard the information are undertaken (45).

On occasion, the issues raised by the information provided by the notifier will cause the Executive to submit information to other government entities or to outside specialists (46). How will confidential data be protected in such a case? Subsection 10(2) prohibits the recipient of the information from using it for any purpose not that of the Executive or the Department of the Environment. The outside party must be informed of his obligation under 10(2). The Executive may make use of written undertakings or contractual obligations and may seek the advice of the notifier (47).

At the time of making a notification, the notifier may indicate that certain information is commercially sensitive and should not be disclosed to anyone outside the Executive or the Department of the Environment (48). After discussions with the notifier, the Executive will decide whether the request is justified. If it is not, the Executive will notify the notifier in writing, with reasons. The notifier will have the option of withdrawing the notification prior to supplying the substance (49). When the notifier has requested non-disclosure, the

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(44) Subsection 10(1).

(45) Guide to the Regulations, p.16.

(46) Ibid, p.16.

(47) Ibid, p.16.

(48) Subsection 10(3).

(49) Guide to the Regulations, p.17.

Executive is obligated under subsection 10(3) to inform the notifier of its intentions before disclosure.

Some information will not be treated as confidential in spite of a notifier's request (50):

a) trade name of the substance;
b) physico-chemical properties;
c) possible ways of rendering the substance harmless;
d) interpretation of toxicity and ecotoxicity tests and the name of the body responsible for the tests (51);
e) precautionary and emergency measures.

Disclosure of Data and Proprietary Rights

It must be kept in mind that "new substance" is not absolute in meaning. The substance continues to be "new" for other manufacturers or importers. They must comply with notification requirements if they wish to supply the substance. The Executive may agree with such notifiers that the latter may refer to the results of studies carried out by previous notifiers. This will only be allowed if the previous notifier agrees in writing and a copy of the agreement is given to the Executive (52). The rationale appears to be to allow commercial arrangements to be made - the previous notifier is able to recover some of the costs involved in testing new substances (53). This recognizes the original notifier's proprietary rights in the test data it has generated. The provision for commercial arrangements alleviates to some extent the problem of cost of testing as a barrier to innovation.

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(50) Subsection 10(3).

(51) Perhaps this requirement is the result of the recent problem in the U.S. where a company which performed such tests on contract for chemical companies and the government had falsified results.

(52) Section 7.

(53) Guide to the Regulations, p.13.

Public Participation

There is no provision in the Regulations for release of information to the public, nor is there provision for public participation in any decision-making process.

Enforcement and Penalties

Enforcement of the Regulations will be made under the powers provided by the Health and Safety at Work Act.

One exception is the regulation of unnotified substances imported into the United Kingdom (54). Contravention of the provision prohibiting such importation will be punishable under the Customs and Excise Management Act 1979 (55).

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(54) Subsection 13(1).

(55) 1979, c.2.

3.1 AUSTRALIA

Australia has a political and legal structure similar to Canada. It is a monarchy and a parliamentary democracy. Unlike Canada, both the lower house, the House of Representatives, and the upper house, the Senate, are directly elected. Australia is a federation of States as Canada is a federation of Provinces. Both Canada and Australia have Territories. The Australian States have sovereign powers similar to those of the Canadian Provinces. As in Canada, the federal nature of the country was weakened by the federal government's decision, decades ago, to collect income tax and dispense money to the States - with a concomitant voice in how such grants should be spent (1).

Australian law derives from the British system as, of course, does Canada's. Australian and Canadian legal precedents are mutually persuasive in each other's courts. In the matter of law reform in Canada, attention is often paid to the relevant Australian experience.

Since October 1, 1981 Australia has had an interim voluntary notification scheme for new chemicals (2). It is administered by the National Advisory Committee on Chemicals, an agency of the Australian Environment Council (AEC). The Council is a national consultative entity comprising the Commonwealth and State Ministers responsible for environmental matters -somewhat analogous to the Canadian Council of Resources and Environment Ministers.

In June of 1984 the AEC announced that agreement had been reached that a mandatory national chemicals notification and assessment scheme should be introduced in 1985. The details of a proposed scheme are contained in a recently released discussion paper (3). The scheme is to be implemented by a "national legal framework", rather than by one specific statute. It is contemplated that the federal government and the State governments will enact complementary legislation. The State and Territory authorities will be the primary control authorities. The federal legislation will require notification of imported chemicals. State legislation will have priority in the establishment of premanufacture notification. If a State elects not to legislate, federal legislation will take priority for premanufacture notification. The New South Wales government has announced its intention to enact an Environmentally Hazardous Chemicals Act as part of the national legal framework. Canada would do well to examine closely the Australian example of cooperation between jurisdictions.

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(1) Encycl. Brit. 2 : 409-410 (1974).

(2) Noted in IRPTC Bull. 5 : 30 (1982).

(3) Australian Environment Council, Discussion Paper on the Proposed National Chemicals Notification and Assessment Scheme, June 1984.

Overview

The proposed Australian scheme will rely heavily on the concepts and methods developed by the OECD chemical program. It is clear that both the EEC and the American systems have been closely reviewed but neither had been adopted *in toto*. A 90 day pre-manufacturing and pre-importing notification period is proposed. A prescribed data package must be submitted for assessment. New chemicals and high priority existing chemicals are covered by the scheme. Additional and follow-up data may be required to be submitted. As in other schemes certain classes of chemicals are exempt, but notably, polymers are subject to a special notification procedure.

The Australian scheme deserves specific consideration from a Canadian perspective because it is new and thus incorporates the most recent OECD concepts and methods and because Australia and Canada share a common legal heritage and a similar federal structure.

Status of Legislation

As the scheme is to be established during 1985, a number of statutes and/or regulations will have to be enacted within the next year. New South Wales appears to be well on its way, as noted *supra*.

Purpose or Scope of the Legislation

The discussion paper expresses concern with exposure of the environment, the workforce, consumers and the general public to chemicals. Legislation will be broad in scope. The federal legislation will cover importing of chemicals, a matter beyond State jurisdiction. As federal legislation will apply in the absence of State legislation, it will presumably have to be at least as comprehensive as State legislation. The proposed scheme is intended to complement existing mechanisms for the control of chemicals (such as those for drugs, agricultural chemicals, etc.).

Effective Date of Notification Requirement

The proposed scheme is to commence during 1985. No specific date is given in the discussion paper. Will all of the Australian States enact legislation to come into effect at the same time?

Type of Notification

A manufacturer or importer intending to introduce a new chemical substance will be responsible for notifying that intention 90 days prior to the intended date of introduction. The scheme is therefore one of pre-manufacturing and pre-importing as "introduction" may occur either by import or domestic manufacturing. The discussion paper does not refer to "marketing" (4).

Notification Time Period

As noted supra, notification must be given at least 90 days prior to the intended date of notification. The notification data is to be initially reviewed within 30 days of receipt. If the notification dossier is incomplete, the formal date of notification will be the date on which a complete package of data is received. A substantive assessment of the submitted material must be completed within the 90 day period. The notification authority may require that further information be supplied. The assessment period may be extended for a further 90 days.

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(4) The discussion paper contains a short glossary in Appendix A. Precise legal definitions must presumably await the drafting of actual legislation. Standardized definitions in the complementary State and federal legislation will be necessary.

Responsibility for Notification

The party proposing to introduce a new chemical is required to submit the notification. This could be either a manufacturer or an importer. The discussion paper states that the scheme will apply to corporations, partnerships, persons and government agencies (5).

Notification Authority

It may be said that the administrative mechanisms necessary to implement a scheme requiring such a high level of inter-agency and inter-jurisdictional cooperation will be difficult to establish. The specific mechanisms are being developed. The proposed scheme involves a "notification authority", "assessment authorities" and "control authorities".

It is proposed that there will be one national notification authority. This authority will ensure that the notification dossier is complete. A completed dossier is then sent to assessment authorities competent to review environmental, occupational health and safety, public health and consumer protection aspects. An assessment report is compiled which will identify risks in these areas and will make recommendations on standards and control measures. Assessment reports along with supporting information will be sent to a "focal point" in each State, Territory and the Commonwealth. The undefined "focal points" will determine necessary control measures to be administereed by the competent control agencies. The control authorities may seek further information from the assessment authorities, or if not so available, directly from the notifier.

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(5) The latter point is unusual. If a State fails to enact legislation and the federal legislation applies, will it bind the State governmental agencies? Certain chemicals may be exempt if national security so requires. Will this be used to exempt military activities in the area of chemical warefare?

Chemicals to be Notified

The proposed scheme applies to "new chemical substances". This will mean any chemical substance not listed in an Australian inventory of chemical substances. A new chemical will be defined as one introduced after January 1, 1984. A "chemical substance" (6) means any chemical element and its compounds or complexes including any chemical element and its compounds or complexes contained in a mixture, any UVCB substance (7) and any naturally occurring substance.

The scheme does not cover "finished articles", radioactive substances or mixtures. More detailed exemptions are noted infra.

Existing chemicals are also covered by the proposed scheme. Existing chemicals with high intrinsic hazard, high exposure potential or about which little is known, may be designated for assessment. Priority listing will be assisted by reference to sources outside Australia. It is proposed that one or more importers or manufacturers will be designated as the party to submit a dossier containing information similar to that required for new chemicals (8).

Apparently negotiations are being conducted so as to inclulde agricultural chemicals and veterinary drugs under the proposed scheme. The administrative mechanisms will have to be modified to include such agencies as the Australian Agricultural Council. Environmental effects of new "therapeutic chemical substances" are covered by the scheme but existing notification procedures (for human health effect evaluation) will be utilized.

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(6) Appendix A of the above-noted discussion paper.

(7) UVCB - any chemical substance of unknown or variable composition, complex reaction products, and biological materials. Does this latter point anticipate the control of biotechnology products?

(8) How will a notifier be designated in an equitable fashion? Will the "deep pocket" theory apply? That is, will large companies be chosen on the theory that they can better afford to compile the necessary data than small companies?

Special notification provisions will apply for new polymers (9). Briefly, all synthetic polymers utilising at least 2% by weight of a new monomer will require notification. A toxic monomer at lower concentration will also be covered by the scheme. A data package specific to polymers will be used. Toxicity testing is for monomers, not polymers. A limited dossier is required for polymers utilizing a new combination of existing monomers. Notification is for an indefinite period for low molecular weight polymers. "Post-reacted synthetic polymers" and biopolymers will be subject to standard notification procedures.

Total Exemptions

The only specific total exemptions referred to in the discussion paper are for reaction intermediates and for research and development chemicals in quantities below 100 kg per annum.

Partial Exemptions

Limited notification is required for:

(a) Small volume chemicals - total amount of less than one tonne in any twelve month period;

(b) Site-limited chemicals - those chemicals, other than reaction intermediates, which do not leave the site of manufacture before being used, and which are manufactured in quantities less than 10 tonnes in any twelve month period;

(c) Research or development chemicals - chemicals used solely for such purposes in quantities between 100 kg and one tonne in any twelve month period.

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(9) Australian Environment Council, Scope and Content of the National Chemicals Notification and Assessment Scheme With Respect to Polymers - Working Paper, May 1984.

Limited notification will require information on the identity, physical/chemical properties, amount introduced, intended use, and a summary of any adverse effects on human health and the environment. Toxicity testing data is therefore not required. Assessment authorities may, however, request further information if there is reason for concern.

Inventory

A new chemical substance requiring notification is one which is not listed in the Australian Inventory of Chemical Substances (AICS). This inventory will include all chemicals imported into or manufactured in Australia in a quantity of at least one tonne by an individual importer or manufacturer in any twelve month period between January 1, 1977 and December 31, 1983. All naturally occurring substances are considered to be existing chemicals and are automatically included in AICS. AICS is not identical in content to the US or EEC inventories but is similar in format. An Australian Core Inventory of Chemical Substances (ACOIN) is being compiled from nominations from 46 companies. Other parties may then nominate chemicals for the final AICS inventory to be published by mid-1985.

How will the inventory be updated? Full notification procedures will apply for any party introducing a particular chemical for five years following the first notification. After five years the new substance will be added to AICS and will thereafter be treated as an existing chemical.

Contents of Notification

A notifier must submit a dossier containing sufficient information to allow an initial hazard assessment of a chemical. The dossier content is to be very similar to the OECD MPD. The discussion paper contains a proforma detailing information required to be submitted. Tests should be carried out in accordance with the OECD Principles of GLP and Guidelines for Testing of Chemicals.

Testing Requirements

Full notification requires test data to be submitted for acute oral, dermal and inhalation toxicity, skin irritation and sensitisation, eye irritation, repeated dose toxicity, mutogenicity, ecotoxicity, degradation and bioaccumulation.

Mutual Recognition of Data

The MAD principle is not directly referred to in the discussion paper. However, the reliance on OECD concepts and methods will facilitate a future application of the principle.

Flexibility in Notification Requirements

If full notification and assessment of chemicals has been made for a chemical under the current interim program then notification will be waived under the mandatory scheme.

Provision is to be made for exceptional circumstances whereby a new chemical may be introduced within less than 90 days of the notification or before a full assessment has been made. Such interim permission may be subject to restrictions. Full assessment procedures must still be carried out subsequent to introduction. "National interest" is a suggested exceptional circumstance.

Test data may be omitted and substitutions may be made if there is scientific justification to do so. This is in accordance with the OECD MPD concept. If there are "sound reasons", an assessment authority may add to or substitute requirements for information.

Notifiers should submit any additional information not required but which is in their possession or which comes to their knowledge which can reasonably be expected to affect the assessment of the submitted material.

Further Testing/Follow-up Measures

Notifiers of all new chemicals (both initial and subsequent notifiers) and of priority existing chemicals must submit a secondary notification for any chemical for which the potential for exposure has changed or for which new knowledge has come to light. The following circumstances will trigger a secondary notification:

(a) Significant new use.

(b) Significant increase in the quantity manufactured or imported. Specific threshold triggers will be 10, 100, 1,000 and 10,000 tonnes per annum.

(c) New knowledge about the hazardous properties of a chemical.

(d) Local manufacture commences for a notified chemical previously imported.

(e) Changes in the method or manner of manufacture which may result in greater environmental or occupational exposure.

(f) Significant change in the composition of a chemical.

The above circumstances are mandatory triggers. Voluntary submissions will be invited. Reassessment may result in further information being required. The discussion paper is not clear whether specific tests may be ordered.

Special Orders

There is no indication that the proposed scheme will include provision for special orders to be made. Monitoring and control functions under the scheme will be in the hands of "control authorities" which will vary according to jurisdiction and control function (eg. consumer protection, environment, etc.). There could well be a wide variety of special orders available under existing or new legislation.

Protection of Confidential Data

Assessments and recommended control measures will be disseminated to control authorities, notifiers, the public (including labour organizations).

The AEC proposes that all information should be available to the public. In accordance with OECD principles some information will invariably be public:

(a) trade or common names
(b) general use information
(c) safe handling precautions
(d) disposal methods
(e) accident safety measures
(f) physical and chemical data (except chemical identity)
(g) summary results and interpretation of health, safety and environmental data.

It is proposed that other data will be public unless a notifier makes a claim for confidentiality for specific data items. The assessment authority must balance the claim against the public interest before accepting or rejecting the claim. No criteria for balancing such interests is given. Government agencies performing assessment functions will have full access to submitted data. Security arrangements will be maintained. Given the decentralized nature of the Australian scheme it will be interesting to see how these will be effected. A time limit may be imposed on the confidential status of data.

Disclosure of Data and Proprietary Rights

Under the proposed scheme, subsequent manufacturers and importers of a previously notified chemical must also submit a full notification until 5 years have passed from the date of the first notification. After 5 years the chemical is no longer "new" having been entered in AICS. A subsequent notifier is free to make arrangements to obtain data from original notifiers. To protect the competitive position of original notifiers, notifiers must certify that they have the right to use any health, safety and environmental data submitted.

Public Participation

As noted the proposed scheme appears to be committed to public disclosure of information, but it remains to be seen how this will be carried out. There is no provision in the scheme for direct participation by the public in any decision-making process.

Enforcement and Penalties

The proposed scheme is not, of course, legislation. No mention is made of specific enforcement and penalty recommendations. The notification scheme will be a mandatory one and will therefore require such procedures. As noted, control authorities are decentralized and will act along jurisdictional lines. A number of legislative initiatives are expected to construct a "national legal framework". Certainly a great effort will be made to enact uniform enforcement and penalty provisions throughout the country.

3.2 AUSTRIA

Austria is a member of the OECD. It is a constitutional federal democracy. The legislative bodies are the National Assembly (Nationalrat) and the Council of States (Bundesrat), both situated in Vienna (1).

It appears that the federal nature of the country's constitution has caused considerable difficulty in implementing environmental laws in general. In principle, the Austrian constitution allows the Federal Government to divide the powers between itself and the nine independent Lander which make up the federation. The federal Ministry of Health and the Environment released a draft Environmental Protection Bill 1975 in May of that year. The Bill proposed to vest legislative powers in the Federal Government in respect (inter alia) of:

> "measures for eliminating and preventing hazards to human health caused by unwholesome effects on the human environment, and measures for monitoring compliance with maximum values for immissions and emissions, including the keeping of records in respect thereof."

In practice, the consent of the Lander for such constitutional legislation seems to be necessary from a political perspective. The Lander rejected the Environmental Protection Bill 1975, not wishing to surrender prospective legislative powers. Instead, the movement is towards employing article 15(a) of the Federal Constitution such that the Federal Government and the Lander may enter into "voluntary sovereign agreements". Such agreements would allow the transfer of powers in the area of environmental protection without the Lander permanently relinquishing a constitutional power (2).

Overview

In 1982 Austria passed the Chemicals Law which is modelled after the German legislation which implemented the EEC Sixth Amendment. An English copy of the Chemicals Law is not readily available. However, a brief overview of the new Austrian legislation is available in a document prepared by Fachverband der Chemischen Industrie Osterreichs (FCIO) which is the Austrian chemical industry federation. The details of the legislation are not readily available. It may be said that this is the first indication of a country not belonging to the EEC adopting the provisions of the Sixth Amendment. Austria is a neutral country yet it is adjacent to the EEC and it is reasonable that such an approach would have been taken. The following is a brief summary taken from the FCIO document.

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(1) Price Waterhouse, Doing Business in Austria (1982).

(2) Kohlegger (1980).

Status of Legislation

The Chemicals Law has been enacted. In 1982 regulations were pending. They were expected to follow the German legislation.

Purpose or Scope of the Legislation

The Chemical Law is concerned with the protection of workers, consumers and the environment.

Effective Date of Notification Requirement

This is not known at this time.

Type of Notification

If the scheme follows the EEC system, as suggested, it will be a form of pre-marketing and pre-importing notification.

Notification Time Period

If the scheme follows the EEC system, as suggested, the notification period will be 45 days.

Responsibility for Notification

Every "new" substance must be notified by the manufacturer or importer. There is no indication of the specific definitions of these terms.

Notification Authority

The specific office is not indicated in the FCIO document, however, it is noted that the Ministry of Health and Environment Protection announced the passing of the Chemicals Law. Presumably the notification authority is an office under that Ministry.

Chemicals to be Notified

Substances and mixtures (non-formulated products) are subject to the Chemicals Law. While they are likely not official definitions, the terms are defined in the FCIO document as follows:

(a) Substances - a chemical element or a chemical compound not treated or processed further in any way, including impurities and additives necessary for marketing.

(b) Mixtures - a mixture blend or a solution of substances not treated or processed further in any way, including impurities and additives necessary for marketing.

The following are not subject to the legislation as they are subject to other regulations:

- pharmaceuticals;
- foodstuffs, feedstuffs and feed additives;
- cosmetics;
- tobacco products;
- wastes;
- waste oils;
- explosives
- gases under pressure

- substances used in the manufacture of medicines;
- pesticides;
- fertilizers.

A substance is "new" and must be notified if it is not in the Inventory of Existing Substances, as mentioned infra. The Austrian system follows the EEC scheme in that notification is "open-ended". A substance is still "new" for subsequent manufacturers or importers.

Expemptions

(a) Quantity exemption - substances produced in amounts of less than one tonne per year need not be notified.

(b) Ten year exemption - if a substance is on the market for more than 10 years, then the "new" substance becomes an "old" substance and is therefore exempt from notification.

Inventory

An Inventory of Existing Substances is to be compiled by the time the Chemicals Law is in effect. A substance will be "new" if it is not in this inventory. It is not clear in the FCIO document to what extent the Austrian inventory will be based on the EEC inventory.

Content of Notification

The following information will be required for the notification of new substances:

(a) chemical identity;
(b) use;
(c) amount to be manufactured (or imported?);
(d) physico-chemical test data;
(e) toxicological test data;
(f) environmental test data.

Testing Requirements

As noted above test results for physico-chemical, toxicological and environmental studies must be submitted. These are referred to in the FCIO document as the "base set" tests. The document states that "if certain limitations regarding amounts of manufacture or import are reached, then the registration authorities can order additional tests".

Mutual Acceptance of Data

Austria is not a member of the EEC and so it might be expected that it would not be capable of partaking in the formal mechanisms for the mutual acceptance of data. Perhaps special arrangements will be made. It is not known if Austria will be complying with the OECD principle of MAD.

Flexibility in Notification Requirements

There are insufficient details provided in the FCIO document to determine if a notifier is allowed to omit or substitute required tests.

Further Testing Requirements/Follow-up Measures

As mentioned, further testing is required if certain levels are reached during the manufacture or importing of a new substance.

Following notification, if a substance is suspected of presenting a danger, further tests can be required.

Special Orders

Following notification, if a danger to man or the environment is established, then the manufacture, marketing or use of a substance can be limited or prohibited altogether.

Protection of Confidential Data

No mention of measures to protect confidential data is found in the FCIO document, but if the Austrian law follows the EEC Sixth Amendment or specifically the German legislation, such provisions would be expected.

Disclosure of Data and Proprietary Rights

In the case of a subsequent notifier, apparently the authorities may not use the documentation provided by the first notifier. The FCIO document indicates that this provision is designed to prevent an initial notifier from being the sole entity to carry the financial burden. However, there is no mention of arrangements between initial and subsequent notifiers being authorized so that costs may be shared, instead of duplicated.

Public Participation

There is no mention in the FCIO document of provisions allowing public participation in decision-making.

Enforcement or Penalties

While not mentioned in the FCIO document, it is reasonable to expect that the Austrain legislation contains such provisons.

3.3 FINLAND

Finland has had a republican constitution since 1919. Legislative power resides with a unicameral Parliament (Eduskunta) and with an elected President. Executive power is shared by the President and the Council of State, or Cabinet. Government ministers are responsible to Parliament. The President has certain decree-making powers of his own. The country is not a federation. The twelve provinces are each under a governor appointed by the President. Finland uses proportional representation in elections and this results in a proliferation of political parties. Governments are therefore mostly coalition ministries (1).

Chemicals constituted 6% of Finland's major exports in 1981 (2).

Finland has two laws of some relevance. There is not however any evidence in the international literature that Finland has established a notification system for new industrial chemicals.

The first law is a 1958 Law on occupational health and safety (3). In 1978 the Finnish Council of State (Cabinet) issued Decree No. 286 on an identification and labelling system for substances hazardous to health. A condensed version of the Decree is available (4).

Decree No. 286 provides that manufacturers, importers and dealers in substances hazardous to health must ensure that such substances are supplied with information on their composition and properties as well as instructions for use and safety in accordance with the Decree and that the substances are packaged and labelled in accordance with the Decree (5).

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(1) Encycl. Brit. 7 : 307-308 (1974).

(2) Encycl. Brit. (1983).

(3) Law No. 299 of June 28, 1958.

(4) Decree No. 286 of April 20, 1978 On An Identification and Labelling System for Substances Hazardous to Health, Finlands Forfattningssamling, April 25, 1978, Nos. 281-287, pp. 628-631. A condensed version appears in Int'l Dig. of Health Leg. 30 : 23-25 (1979).

(5) Section 1 - Decree No. 286.

Decree No. 286 applies to "substances hazardous to health", meaning basic substances and compounds as well as mixtures and products containing such basic compounds, which when used in the occupational environment are (6):

(a) toxic, corrosive, irritant, generally allergenic, carcinogenic or otherwise harmful to health;

(b) explosive, highly reactive, oxidizing, combustible or flammable; or

(c) radioactive.

The Decree is not applicable to pharmaceutical specialities, substances or products sold as medicaments in pharmacies, alcoholic drinks or tobacco products.

Information is provided to the recipients of the substances (7):

(a) particulars of the trade name;
(b) intended purpose;
(c) manufacturer or importer of the substance;
(d) the nature of the substance;
(e) its quantity;
(f) particulars of those chemical and physical properties of the substance which may endanger employee's health;
(g) particulars of the health hazards caused by the substance;
(h) where necessary, any first-aid measures;
(i) a description of preventative measures designed to avoid hazards;
(j) handling and storage instructions.

Similar information must be provided for hazardous mixtures or products. A number of exceptions are provided for (8). If the supplier knows that the substance will be used for a specific purpose, special precautionary measures must be provided if necessary (9). Other provisions of Decree No. 286 deal more specifically with labelling and packaging.

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(6) Section 2 - Decree No. 286.

(7) Section 3 - Decree No. 286.

(8) Section 5 - Decree No. 286.

One provision of the Decree requires the Ministry of Social Affairs and Health to draw up a list of substances which must have certain information on the packaging (10). Such a list has been issued, the main portion of which has 1180 names (11).

An express provision for notification of substance, whether new or existing, to the government is not apparent in the condensed version of Decree 286 which is readily available. Perhaps such provision exists in an associated Decree. One wonders where the government would otherwise obtain the information for, and the identity of, the substances on its list.

Finland enacted a Law on poisons in 1969 (12), but a full English version of this Law is not readily available. In 1980 an extensive Ordinance No. 492 was issued pursuant to the Law on poisons (13).

Ordinance No. 492 does require that an application to import or manufacture "poisons" for use in the protection of wood or for impregnating or preserving textile or paper products must include details of toxicological tests carried out on the product and its active components as well as the degradability and environmental effects of the active substance (14).

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(9) Section 6 - Decree No. 286.

(10) Section 8 - Decree No. 286.

(11) Decree No. 409 of June 6, 1978, Finlands Forfattningssamling, June 9, 1978, No. 409, pp. 861-892. The contents of the Decree are noted at Int'l Dig. of Health Leg. 30 : 24 (1979).

(12) Law No. 309 of May 16, 1979; a brief note appears at Int'l Dig. of Health Leg. 21 : 295 (1970).

(13) Ordinance No. 492 of June 27, 1980 On Poisons, Finlands Forfattningssamling, July 1, 1980, Nos. 486-494, pp. 1309-1316. A condensed version, taking into account amendments made by Ordinance No. 58 of January 23, 1981 (Finlands Forfattningssamling, January 28, 1981, Nos. 51-60, p. 93), appears at Int'l Dig. of Health Leg. 32 : 288-290 (1981). Further amendments were made in 1982: Ordinance No. 364 of May 21, 1982, amending sections 20 and 32 of Ordinance No. 492, Finlands Forfattningssamling, May 24, 1982, Nos. 360-376, p. 788; note of which appears at Int'l Dig. of Health Leg. 34 : 623 (1983). Ordinance No. 492 is noted in IRPTC Bull. 4 : 23-24 (1981) and Ecochem Bull. No. 170 (1980).

Other than the latter provision there is no apparent notification requirement in the condensed version of Ordinance No. 492 available. The Ordinance does provide for a licence system for the importers and manufacturers of and traders in poisons. Poisons are to be listed by the Ministry of Social Affairs and Health (15). A Decree issued on the same day as Ordinance No. 492 (16) provided that the list in Ordinance No. 492 is to comprise a portion of the lists in Decree No. 409 (the lists used for Decree No. 286, supra).

Ordinance No. 492 does provide that importers are obliged to give customs authorities necessary information for the supervision of the importing of poisons. The customs authorities then inform the National Board of Health of the type and amount of Class One poisons and the name and address of the importer (17).

As in the case of Decree No. 286, one suspects that there are general provisions in existence requiring information to be submitted to the government under Ordinance No. 492, or the parent Law of 1969, other than the provision relating to poisons in textiles and wood products in the Ordinance.

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(14) Section 2 - Ordinance No. 492.

(15) Section 1 - Ordinance No. 492.

(16) Decree No. 493 of June 27, 1980, Finlands Forfattningssamling, July 1, 1980, Nos. 486-494, p. 1317; noted in Int'l Dig. of Health Leg. 32 : 290 (1981).

(17) As noted in IRPTC Bull. 4 : 23-24 (1981).

3.4 ICELAND

Iceland is a parliamentary democracy with an elected President as head of state. Parliament (Althingi) is divided into upper and lower houses. The executive branch is headed by a Cabinet consisting of a Prime Minister and about half a dozen other ministers.

Iceland has a relatively high standard of living and one of the highest levels of public health in the world. The Icelandic people are relatively homogeneous in wealth, education, language and ethnicity (1).

Chemicals were not listed in the country's major exports in 1981 (2).

In 1968 Iceland passed Law No. 85 on poisonous and dangerous substances (3). It came into force on January 1, 1970. Under the Law "poisons" and "dangerous substances" are defined to mean substances contained in lists annexed to the Law as well as compounds and products containing such substances if they are a risk to man and animals.

Law No. 85 creates a Poisonous Substances Board, the chairman of which must be a toxicologist. The Board is responsible for updating the lists as well as responsible for providing recommendations to the competent Minister for subsequent regulations concerning the prohibition, use, packaging and labelling of poisonous and dangerous substances.

The Law controls the acquisition, purchase, sale, manufacture and importation of poisonous substances. A licencing system is established by the Law.

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(1) Encycl. Brit. 9 : 174 (1974).

(2) Encycl. Brit. (1983).

(3) Law No. 85 of December 31, 1968 On Poisonous Substances and Dangerous Substances, Stjornartidindi, Part A, 1968, No. 18, pp. 331-347. A condensed version appears at Int'l Dig. Health Leg. 22 : 470-471 (1971).

Over the years a number of Orders and Notices have been issued regarding the licencing system, exemptions, manufacturing, labelling, supervision and working procedures of the Board (4). Unfortunately full versions of these are not readily available in English.

Generally, there is no evidence in the literature that Iceland has established a notification system for new industrial chemicals. The legislation discussed supra is similar to the type of legislation in existence in other countries such as Switzerland, New Zealand, Sweden, etc. Presumably some of the subsidiary Orders and Notices under the Law provide for some information to be submitted to the government in order to obtain a licence but such information is probably not as extensive as that required under the notification systems established under the EEC Sixth Amendment for example.

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(4) See Appendix.

3.5 JAPAN

Japan is a centralized, non-federal democracy. The Constitution of 1947 established the separation of legislative, executive and judicial powers, placing sovereignty with the people and the Emperor as the symbol of state.

Legislative power is vested in the Diet, a two-chamber parliamentary system consisting of the House of Representatives and the House of Councillors. As of 1983 the Liberal-Democratic Party had been in power for more than thirty years.

The Prime Minister is elected by the House of Representatives from among the members of the Diet. Executive power rests with the Cabinet, which is chosen and headed by the Prime Minister. Twelve of the Cabinet members head the dozen major ministries (1).

A thorough description of the historical development of environmental law in Japan has recently been published (2). Of particular interest is the continuing power of the ministerial bureaucracies to control the legislative process. The Japanese ministries are apparently insulated from political concerns to a large degree. There is considerable jurisdictional rivalry between individual ministries. The latter foster loyalty and solidarity within the ministry, hire for life and recruit only from the bottom of the organization. Interministerial cooperation has been a problem. Conflicts have usually been resolved through consensus, a concept which appears to have strong roots in Japanese culture (3).

For many years the Ministry of Health and Welfare has been administering the Poisonous and Deleterious Substance Control Law (Law No. 303 of 1950). This law regulated the classification, registration, importation, sale, etc. of recognized hazardous substances. The latest available amendment to the law was Law No. 103 of June 26, 1972. Despite its name, the Law does not consider the notification of new chemicals. There is no indication that Law was repealed with the passage of the Chemical Substances Control Law of 1973.

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(1) Constitutional material in the preceding three paragraphs is taken from Price-Waterhouse (1983) - Japan, and Gresser et al. (1981) at p. 234.

(2) Gresser et at. (1981).

(3) The "consensus" analysis in Gresser et al. has been severely criticized by Aronson (1983).

Japan was one of the first nations to pass legislation requiring notification and testing of new chemicals. The Law Concerning the Examination and Regulation of Manufacture, etc., of Chemical Substances (Law No. 117 of 1973), abbreviated as the Chemical Substances Control Law was approved at the 71st Special Session of the Diet (4).

This Law predates both the EEC Sixth Amendment and the American TSCA. The need for such legislation arose from Japan's early experience with PCBs and so the Law's purpose has been to identify PCB-like chemical substances based on a premanufacturing or preimporting notification system. For this reason the Law emphasizes PCB qualities such as persistence, bioaccumulation and chronic toxicity (5).

There are three entities concerned with the operation of the Chemical Substances Control Law. The major responsibility for administering the Law rests with the Ministry of International Trade and Industry (MITI). MITI shares with the Ministry of Health and Welfare (MHW) many functions. MHW emphasizes chemical products rather than substances in its jurisdiction. It also tests for carcinogens among the substances referred to it by MITI. The Japanese Environment Agency monitors the effect of chemicals in air and water. The Agency's direct role in the operation of the Law is minimal. MITI's direct responsibilities include the control of production and import of "specified chemical substances" (6).

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(4) The Law Concerning the Examination and Regulation of Manufacture, etc., of Chemical Substances, Law No. 117 of 1973. This is normally abbreviated to the Chemical Substances Control Law. A complete version of the Law in English, along with several Orders, is to be found at (Reference) Int'l Env. Rep. 91 : 6401-6426 (1978). For an edited version of Law No. 117 see: Int'l Digest Health Leg. 28 : 293-302 (1977).

(5) Kubota (1979).

(6) (Reference) Int'l Env. Rep. 91 : 0101-0106 (1979) and Kawasaki (1980).

The third entity, the Environment Agency (7), is an executive body established under the Prime Minister's Office. It is headed by a Director-General who is a member of Cabinet (8). The Agency's main functions are planning and coordination. As of 1981, the Agency appears to have been hampered in its activities by rivalry between and with the traditional ministries (9).

Throughout the Chemical Substances Control Law there is reference to details of the Law being put into operation through the issuance of:

a) Cabinet orders;
b) Ministerial orders of MHW & MITI; and
c) Prime Minister's Office orders.

A list of the various orders and guidelines which have been issued pursuant to the Law is found in the Appendix *infra*.

A phenomenon which is not common in Anglo-Canadian legal tradition is the Japanese "administrative guidance" (gyoseishido), a bureaucratic right to issue orders. These orders need not be made public. MITI has apparently used these kinds of orders to halt production of some chemicals found to have PCB characteristics (10).

It should be noted that the Chemical Substances Control Law is only one of the numerous laws regulating hazardous substances in Japan. In the occupational health and safety area, there is apparently a requirement for notification and testing of new chemicals. The emphasis is on the carcinogenicity and mutagenicity of chemicals, as opposed to emphasis on chronic toxicity and environmental effects of chemicals in the Chemical Substances Control

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(7) An interesting historical account of the Environment Agency has been given by Gresser *et al*. (1981) at pp. 26-27.

(8) Gresser *et al*. (1981) at p. 234.

(9) Ibid. at p. 242.

(10) (Reference) Int'l Env. Rep. 91 : 0101-0106 (1979). Gyoseishido is also discussed at length in Gresser *et al*. (1981).

Law. A summary of the Ordinance (11) implementing the Industrial Safety and Health Law (12) has recently been published (13) as follows:

1. The investigation of the toxicity of chemicals should include tests for carcinogenicity and mutagenicity

2. Manufacturers and importers of new chemicals should submit the results of the tests for carcinogenicity and mutagenicity and the methods for production and handling them to the Minister of Labour and the latter should be satisfied that the workers exposed to the chemicals will not be adversely affected.

3. Details of all new chemicals substances which are manufactured or imported should be made public.

4. The Minister of Labour may request manufacturers or importers of existing chemicals which may seriously affect the health of workers to submit the results of toxicity tests. These tests shall be on carcinogenicity in experimental animals by the oral or inhalation route.

5. Where such tests indicate possible adverse effects on workers, the manufacturers and importers shall take prompt measures to safeguard the workers.

From a schematic description of Japan's chemical control laws (14) it would appear that the occupational health and safety legislation dealing with carcinogens and mutagens covers all chemical classes: drugs, cosmetics, food additives, agricultural chemicals and industrial chemicals.

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(11) Ordinance No. 2 of January 27, 1979, Ministry of Labour.

(12) Kampoo, January 27, 1979, No. 15607.

(13) IRPTC Bull. 3 : 22 (1980). See also the summary in Int'l D. of Health Leg. 30 : 816 (1979).

(14) Kawasaki (1980), p. 140, chart 1.

Overview

The chief characteristics of the Japanese system are as follows:

a) The government performs some of the tests on a new chemical, in distinction to the EEC and U.S. systems.

b) The government designates new chemicals as "safe" or as a hazardous "specified chemical substance". In other words, there is an obligation on the part of the government to approve or disapprove, in distinction to other systems which only require disapproval.

c) The characteristics of a "safe" chemical are non-persistence and non-bioaccumulation in the environment rather than the chemical's lack of mammalian toxicity.

d) The notification and testing requirements are part of an overall scheme involving control of hazardous "specified chemical substances" and the development of an inventory of existing chemical substances.

Status of Legislation

The Chemical Substances Control Law has been in effect for ten years. As mentioned *supra*, a number or orders and guidelines have been issued pursuant to the Law. Two reviews of the Law have been published, both of which provide statistics for the numbers of chemicals screened over the years as well as procedural flowcharts (15).

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(15) Kawasaki (1980) and Kubota (1979).

Purpose or Scope of the Legislation

The Law is designed to prevent chemicals from polluting the environment which are harmful to human health, and which are persistent (16). The legislation is environmentally oriented. It is not occupational health and safety legislation.

Effective Date of Notification Requirement

The Law came into effect on April 16, 1974 (17) although some provisions in the Appendix to the Law, having to do with establishing the List of Existing Chemical Substances, came into effect on October 16, 1973.

The ministerial order providing the details of the notification scheme did not come into force until June 10, 1974 (18).

Type of Notification

The Japanese system requires pre-manufacturing and pre-importing notification for new chemical substances (19). For substances designated as hazardous, or "specified chemical substance", there is a separate pre-manufacturing and pre-importing application requirement (20) and a pre-use notice requirement (21). The Japanese system therefore covers "new" and existing chemical substances.

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(16) Article 1.

(17) Six months after date of promulgation, October 16, 1973. Article 1 of Appendix to Law No. 117 of 1973.

(18) Order of Ministers of MHW & MITI promulgated April 19, 1974 and amended June 10, 1974; see Appendix.

(19) Article 3, para. 1.

(20) Article 6, para. 1 and Article 11, para. 2, respectively.

(21) Article 15, para. 1.

Notification Time Period

Neither the Law nor the Orders issued pursuant to it indicate how far in advance of manufacturing or importing notification must be given. This is because both the Sixth Amendment and the U.S. TSCA allow marketing or manufacturing after 45 and 90 days, respectively, after notification, unless the government states otherwise, ie: disapproves. Under the Japanese system, the relevant time period is three months from receipt of the notice. During this time period the government must decide whether the new chemical is:

a) "safe" ie ... approval;
b) "hazardous", ie ... disapproval; or
c) it is not clear whether it is safe or hazardous (22).

Responsibility for Notification

The manufacturer or the importer is responsible for notification. The Law does not elaborate on the terms "manufacturer" or "importer".

Notification Authority

The notifier must submit the notice to MHW and MITI (23). The latter are required to forward immediately a copy of the notice to the Director of the Environment Agency (24). The latter can request further information from MHW and MITI concerning their reasons for their approval, etc. and may express his opinion before a final decision is reached by MHW and MITI (25). So it would appear that the primary authorities are MHW and MITI with the EA serving in an advisory capacity.

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(22) Author's quotation marks. The Law does not actually use the terms "safe" or "hazardous". Time period is referred to in Article 4, para. 1.

(23) Article 3, para. 1.

(24) Article 3, para. 2.

(25) Article 4, para. 5.

For manufacturing or importing a "specified chemical substance" (not a "new", but an existing substance), the application is made to MITI and not MHW (26). To use a "specified chemical substance" commercially, a person must give notice to the "competent minister" (27).

Chemicals to be Notified

A "chemical substance" is "a compound obtained by causing a chemical reaction to occur in elements, a compound and/or compounds" (28). The latter portion of the definition "and/or compounds", suggests that mixtures or formulations are included in the meaning of "chemical substance". The definition does not include:

(a) radioactive substances;
(b) specified poisons in the Poisonous and Deleterious Substance Control Law (29);
(c) stimulants in the Stimulants Control Law (30);
(d) narcotics in the Narcotics Control Law (31).

Notice must be given for the manufacturer or importer of new chemical substances. The following are not "new" (32):

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(26) Article 6, para. 1 and Article 11, para. 2.

(27) Article 15, para. 1.

(28) Article 2.

(29) Article 2, para. 3 of that Law refers to a Schedule C. This schedule contains a number of thiophosphates and pyrophosphates.

(30) Article 2, para. 1 of that Law (1951, Law No. 252) and stimulants' raw materials in para. 5 of Article 2 of that Law.

(31) Article 2, para. 1 of that Law (1953, Law No. 14).

(32) Article 3 of Law No. 117 of 1973.

(a) chemicals approved as "safe" after notification and review;
(b) "specified chemical substances";
(c) chemicals listed in the List of Existing Chemical Substances (33).

In this respect the Japanese system is similar to that of the U.S. as opposed to the European system where "new" does not have an absolute meaning and subsequent manufacturers and importers of a "new" substance must notify the competent authority.

Total Exemptions

The following new chemical substances are exempt from the notification requirements:

(a) Testing & research - if the new chemical substance is to be manufactured or imported for testing and research purposes (34).

(b) Reagent - if the new chemical substance is to be manufactured or imported as a reagent - meaning a chemical used for the detection or estimation of a substance by chemical methods, for experiments in synthesis of a substance, or for measurement of the physical characteristics of a substance (35).

Partial Exemptions

The Law allows for other exemptions "as prescribed by government orders" (36). Orders have been made under this proviso but the exemptions are actually a different type of notification:

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(33) See the section, infra, on Inventory.

(34) Article 3, para. 1.

(35) Ibid.

(36) Ibid.

(a) Intermediate of medical supply - notification in the normal course is not required for the manufacture or import of a new chemical substance as an intermediate of medical supply authorized under the Pharmaceutical Law (37). However, in a seperate ministerial order (38), such substances must be reported using a different form which indicates the route through which the substance is converted to a medical supply. The form is submitted to MHW and MITI.

(b) Small quantity - a manufacturer or importer of a quantity of a new chemical less than 100 kg per year is exempt from the normal notification procedure. However, the person must satisfy MHW and MITI in advance, through a submission of a different form, that the quantity will not exceed 100 kg and that the chemical, judged "from already available information", offers no fear of causing pollution or human health injuries (39). The total amount manufactured or imported annually may not exceed 1000 kg.

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(37) This exemption is contained in Cabinet Order No. 202, Article 2 (see Appendix). The Pharmaceutical Law is Law No. 145, 1960, and the relevant provisions are Article 12, para. 1 and Article 18, para. 1.

(38) Ministerial Order of MHW and MITI No. 1 (see Appendix), Article 3. The required form is Form No. 2, appended to the Order. The form requires the following information:
(a) name of substance;
(b) formula;
(c) route to medical supply;
(d) amount to be manufactured/imported annually;
(e) name and place of business/manufacture (if imported).

(39) Cabinet Order No. 202, Article 2. The form is prescribed in Ministerial Order of MHW and MITI No. 1., Article 4- Form No. 3. The information required in Form No. 3 is similar to Form No. 2, supra, footnote (38). There are provisions in Article 4 regarding time periods for submission of notice but they suffer from poor translation from Japanese and are unintelligible.

Importing

There are special documentation procedures in effect which apply to the importation of new chemical substances which are too intricate to cover in this report (40).

Inventory

As mentioned, supra, a chemical is not "new" if it is listed in the List of Existing Chemical Substances. This inventory is published by MITI. The Appendix to the Law (41) required that MITI prepare a list of names of chemicals being manufactured or imported commercially (with the exception of research chemicals and reagents) at the date of promulgation of the Law, October 16, 1973. The list was to be published by January 16, 1974. A handbook in English has been published which contains the List of Existing Chemical Substances (42). Provision was made for amendment of the List through public participation for one month (until February 16, 1974) and the amended List was to be republished by March 16, 1974, one month before the Law, as a whole, came into effect (43).

There is no provision for the List to be amended with the on-going approval of new substances. The List is "cast in stone". However, the new chemicals approved are published by MHW and MITI (44). A substance is not "new" if it has previously been approved. Therefore, the approved chemicals must constitute a subsidiary "list" to the List of Existing Chemical Substances. As of October 30, 1978 a list of new chemicals approved as being biodegradable, nonbioaccumulative and not harmful to human health if ingested continuously, was published (45). A more current list is not readily available (because it is confidential).

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(40) See Customs Clearance Procedures of July 19, 1974 and guidelines issued July 30, 1974 "On the Import of Products Designated by the Enforcement Order of the Chemical Substances Control Law" in Appendix, infra.

(41) Appendix to Law No. 117, Article 2, para. 1.

(42) The Chemical Daily Co., Ltd. Handbook of Existing Chemical Substances, Tokyo (1977).

(43) Appendix, Article 2, paras. 2, 3, and 4.

(44) Article 5, para. 3.

Content of Notification

Notification of a new chemical substance is made by submitting two copies of Form No. I to MHW and MITI. The Form requires the following information (46):

(a) name of new chemical substance;
(b) structural or rational formula (if neither is known, an outline of the process for manufacture is required);
(c) physical properties, chemical properties and composition;
(d) use;
(e) the amount expected to be manufactured or imported annually during the three years after "commencement of the business";
(f) if manufactured, location of the business;
(g) if imported, location of manufacture;
(h) attachment of documents which will assist MHW and MITI in their decision whether the substance is "safe" or "hazardous".

Testing Requirement

The decision whether a new chemical should be approved or not is a two-step process. There is an initial decision whether the substance is biodegradable, bioaccumulative or harmful to human health (and whether its natural degradation products have those characteristics). This decision is based on "already available information" ie: formula, physical and chemical properties and "influence upon organisms" (47).

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(45) (Reference) Int'l Env. Rep. 91 : 6420-6426.

(46) Ministerial Order of MHW and MITI No. I, see Appendix.

(47) Order Prescribing the Items of the Test Relating to New Chemical Substances of July 13, 1974, see Appendix.

If it is not clear from the intial review whether the substance has the above properties, MHW and MITI "must promptly determine on the basis of the results of tests carried out for the new chemical substance" whether it does have those properties (48). Those tests have been described in an Order (49) as follows:

(a) tests on the degradability of the chemical by microorganisms for the decision whether it has "the property of persistence against natural effects";

(b) tests on the degree of accumulation of the chemical in the bodies of fish and shellfish for the decision whether the chemical is easily accumulated in organisms;

(c) tests on general toxicity, tests on special toxicity, pharmacokinetics study and general biological tests of the chemical for the decision whether the chemical, when ingested continuously, causes harmful effects on human health.

The detailed methods for these three categories of tests have been published (50). The tests are extensive. Curiously enough, neither the Law nor the Orders which are readily available, state clearly that the manufacturer or importer must undertake any of the above tests. There are comments in the literature (51) that the manufacturer is responsible for conducting the persistence and bioaccumulation tests while the government conducts the toxicity tests. Testing by the government is done at the notifier's expense.

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(48) Article 4, para. 2.

(49) Order of July 13, 1974, footnote (46).

(50) See Appendix. They have been discussed in some detail in Kubota (1979).

(51) Kawasaki (1980) p. 142 and 149 and at p. 7-12 in a section titled "The Japanese Chemical Control Law" in Springborn (1982).

Mutual Acceptance of Data

The Japanese system is not part of an international system such as the EEC Sixth Amendment. From the information readily available, there is no indication of the application of the MAD principle.

Flexibility in Notification Requirements

Perhaps connected to the cultural principle of "consensus", there is a practice of submitting chemicals to a pre-notification test conducted in the same laboratory as the actual notification test. Chemicals which do not pass the pre-notification test are not usually formally submitted (52).

Further Testing Requirements/Follow-up Measures

The two-step review process has been discussed supra. Further testing is done as part of the notification process. Once a chemical has been approved as "safe" there does not appear to be a mechanism for further testing. If a substance is found to be "hazardous", ie: a "specified chemical substance" there are extensive provisions for its regulation (53).

Special Orders

A form of "follow-up measure" is found in the miscellaneous provisons of the Law (54). If there is sufficient reason to suspect that a chemical other than a specified chemical substance may be hazardous, a competent Minister may recommend various restrictions on the manufacture, import or use of the substance.

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(52) (Reference) Int'l Env. Rep. 91 : 0105-6 (1979).

(53) Section 3, Articles 6-22.

(54) Article 23.

There are a number of broadly worded provisions allowing the government "to let" persons report on their business activities, allowing inspections, and providing for the keeping of records (55).

Protection of Confidential Data

The government is required to publish the name of a chemical found to be "safe" (56). There does not appear to be a mechanism for publishing details of a PMN. Consequently, there is no mechanism evident for the protection of confidential business data - it, presumably, is not needed. An overall impression is that the system is not run with a view to public participation; nor is it necessary under the Japanese system for subsequent manufacturers or importers to use data generated by a previous notifier (because subsequent notification is not necessary). The system may be "inherently secretive".

Enforcement and Penalties

If a person fails to give the required notice or if a person gives notice but manufactures or imports a new chemical before approval is given, that person is subject to a penalty of a fine of up to 100,000 yen, up to a year in jail, or both, if convicted (57).

There are other penalties attached to violating provisions relating to specified chemical substances, keeping records, obstructing inspections, etc. (58).

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(55) Section 4.

(56) Article 4, para. 3.

(57) Article 35.

(58) Articles 34, 36, 37, 39.

3.6 NEW ZEALAND

New Zealand shares a common legal and constitutional heritage with Australia and Canada. It is a monarchy and a parliamentary democracy. The government leader is the Prime Minister who presides of a Cabinet of ministers, as in Canada. Unlike Australia and Canada, New Zealand is not a federal state - there are no provinces or states. The country is strongly centralized as a result. As well, New Zealand has a single-chamber Parliament, the House of Representatives. Moreover, state intervention in the economy has a long history in New Zealand. The country might be referred to as a welfare state; the government bureaucracy is relatively extensive (1).

The chemical industry does not appear to be significant. Chemicals were not listed among the country's major exports in 1981 (2).

As a result, New Zealand may have more concern for the control of imported chemicals than for new chemicals developed by an indigenous industry.

Status of Legislation

New Zealand has not enacted specific legislation establishing a notification system for new industrial chemicals. Instead, the country has enacted the Toxic Substances Act 1979 (3). Recently, the Toxic Substances Regulations 1983 (4) have been issued pursuant to the Act. The 1983 Regulations are not relevant to our purposes.

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(1) Encycl. Brit. 13 : 48-49 (1974).

(2) Encycl. Brit. (1983).

(3) Toxic Substances Act 1979 No. 27, Stat. of New Zealand, 1979, Vol. 1, pp. 449-505; enacted October 19, 1979. Amended: 1979, No. 124, s.12; 1979, No. 125, ss. 2(3), 18(2); 1983, No. 98.

(4) Toxic Substances Regulations 1983, S.R. 1983/130, pp. 1-52; issued July 25, 1983.

Purpose or Scope of the Legislation

The New Zealand legislation is similar to the Swiss legislation in that its primary purpose is to regulate trade in toxic substances rather than set up an evaluation procedure for "new chemicals". Most of the provisions in the New Zealand legislation are concerned with advertising, packing, storing, handling, transporting and labelling toxic substances. A licencing system is established.

The New Zealand legislation does have a notification provision. Section 32 of the Act provides:

> ... every person who intends to import or manufacture or prepare or pack any toxic substance that he has not previously imported into or manufactured or prepared or packed in New Zealand ... or to import or manufacture or prepare or pack any toxic substance bearing a common name, chemical name, or trade name under which he has not previously distributed the toxic substance in New Zealand, shall, before so importing or manufacturing or preparing or packing the toxic substance, notify the Director of his intention.

The harm which the Act attempts to prevent is both damage to human health and to the environment.

Effective Date of Notification

The Act came into effect at some time in 1979 (5).

Type of Notification

The notification scheme could be referred to as pre-manufacturing and pre-importing notification. From the wording of Section 32 of the Act it might also be referred to as pre-preparing or pre-packing notification. "Prepare" means to dilute, or to convert chemically to another substance, preparation, mixture or compound at any time before the toxic substance is packed for sale. "Pack" means to enclose in a container for the purpose of storage or sale (6).

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(5) Toxic Substances Act Commencement Order 1979, S.R. 1979/276. A copy of this Order was not readily available.

Notification Time Period

None is given in the Act. Notification must simply be given prior to the manufacture, import, preparation or packaging of a "new" toxic substance (7).

Responsibility for Notification

Responsibility for notification rests with every person who intends to manufacture, import, prepare or pack a "new" toxic substance (8).

Notification Authority

Notification must be made to the Director of the Division of Public Health in the Department of Health (9).

Chemicals to be Notified

The notification provision applies to "new" toxic substances; not new substances.

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(6) Subsection 2(1).

(7) Subsection 32(1).

(8) Ibid.

(9) Subsection 32(1) and subsection 2(1).

A "substance" means any natural or artificial substance whether in solid or liquid form or in the form of a gas or vapour (10).

A "toxic substance" includes (11):

(a) "deadly substances", "dangerous substances", "standard poisons" and "harmful substances", all of which phrases refer to substances declared to be such by Order in Council (12);
(b) pesticides, herbicides, etc.;
(c) tobacco;
(d) any other substance;

provided that (in a-d above) when swallowed, inhaled, or injected into or otherwise absorbed by the human body, is likely by reason of its toxic properties, to destroy life or be injurious to health.

(e) any other substance that, by reason of its chemical or biochemical properties, may directly or indirectly adversely affect the environment.

A toxic substance includes any substance, preparation, mixture, compound, or article containing, otherwise than in a toxicologically insignificant quantity, the toxic substance (13).

Aside from the Section 32 notification system, the Act provides that notice must be given to port authorities for class 6 poisonous substances or class 8 corrosive substances (14) arriving in New Zealand by sea (15). A minimal amount of information is required, such as the identity and quantity of the substance imported. This notification provision is in addition to Section 32. It applies to existing substances as the substances must, of course, have had the above classifications made applicable to them.

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(10) Subsection 2(1).

(11) Ibid.

(12) Section 7. The Minister of Health makes such decisions on advice from the Toxic Substances Board.

(13) Subsection 2(2).

(14) Section 35 - Regulations.

Exemptions

The following are not included in the meaning of "toxic substance":

(a) tobacco, excepted as provided for in specific provisions not related to notification (16);
(b) food;
(c) a restricted drug;
(d) a controlled drug;
(e) a radioactive material.

The following toxic substances are expressly omitted from the notification provision in the Act (17):

(a) if the substance is registered as a pesticide or its use is authorized as an experimental pesticide;
(b) if the substance is licenced as a veterinary substance;
(c) if an application is pending for either (a) or (b) above;
(d) if the substance is for the purposes of teaching, research, or investigation in any laboratory in New Zealand (18).

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(15) Section 43 - Act.

(16) Subsection 2(3).

(17) Subsection 32(3).

(18) Subsection 32(8).

Inventory

There is no apparent provision for an inventory of existing toxic substances which could be used to define "new" as opposed to "old" toxic substances. An inventory is not needed. A person must notify the competent authority with respect to toxic substances new to that person, not generally new to the marketplace. How does the government know? Presumably only after the fact. However, the competent authority may request information regarding a substance it "suspects to be a toxic substance" (19).

Content of Notification

A notifier must submit the following to the competent authority:

(a) notification of the intention to manufacture, import, prepare or pack a toxic substance new to the notifier (20);
(b) details of the composition of the substance (21);
(c) the purpose for which the substance is intended to be used (22);
(d) the method of use (23);
(e) such other particulars as the Director may require (24).

Testing Requirements

The Act does not provide for mandatory testing requirements upon notification.

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(19) Subsection 32(5).

(20) Subsection 32(1).

(21) Subsection 32(2)(a).

(22) Subsection 32(2)(b).

(23) Subsection 32(2)(c).

(24) Subsection 32(2)(d).

Mutual Acceptance of Data

There is no such principle contained in the New Zealand Act.

Flexibility in Notification Requirements

The notification requirements are not arduous and therefore a provision for the omission or substitution of date was probably considered unnecessary.

Further Testing Requirements/Follow-up Measures

"From time to time" (presumably meaning other than upon initial notification) the competent authority may require any importer, proprietor, manufacturer, seller, preparer, or packer to provide any of the particulars required to be submitted upon initial notification (25). The net that this provision casts is wider than that in the legislation of other countries in that it refers to persons other than manufacturers or importers.

In addition, "from time to time", the competent authority may also require the following (26):

> such information as the importer, proprietor, manufacturer, seller, preparer or packer has in his possession as to the date of any sale of that substance, the quantity so sold and the identity of the recipient.

This provision also applies to any substance the competent authority suspects may be a toxic substance.

As follow-up measures, these provisions require the submission of information already available to the notifier. They do not require testing to be done, nor do they expressly require test data. They only way in which test data could be obtained is if such information is included in the meaning of "such other particulars".

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(25) Subsection 32(4).

(26) Subsection 32(5).

Special Orders

The Minister of Health may prohibit the importation, manufacture, sale, possession or use of any toxic substance either absolutely or subject to "such conditions as he thinks fit", for any specified period not exceeding one year.

Such prohibition is made on the recommendation of the Toxic Substances Board (27).

Protection of Confidential Data

Information submitted to the competent authority will be treated as confidential if the notifier requests, except for the purposes of the administration of the Act (including an investigation or proceedings in respect of an alleged offence) or any other purpose approved by the Minister of Health (28).

Disclosure of Data and Proprietary Rights

Other than disclosure of data for the purposes mentioned above, there is no mechanism for disclosure of data. The quantity and quality of information in the New Zealand system is minimal. Proprietary rights are only significant if a notifier must go to the expense of performing tests on a new substance. Such is not the case in New Zealand.

Public Participation

There is no provision for public participation in New Zealand's notification system.

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(27) Subsection 33(1).

(28) Subsection 32(6).

Enforcement and Penalties

It is an offence to fail to comply with any of the provisions relating to notification (29). The Act provides for a wide variety of enforcement powers such as search and seizure. The penalty for committing an offence is imprisonment up to 3 months or a fine not more than $500, although if the offence is a continuing one, a further fine not to exceed $50 per day for every day during which the offence has continued (30). The fines pertaining to offences in New Zealand are not particularly draconic. The Act does provide for liability for a principal for acts of agents (31).

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(29) Subsection 32(9).

(30) Subsection 62.

(31) Subsection 63.

3.7 NORWAY

Norway is a constitutional hereditary monarchy. The King acts as administrative head of government and selects the Cabinet. The legislative body is the elected Storting. The country is not a federation. There are 20 counties, each with a governor appointed by the Cabinet (1).

Chemicals constituted 6% of Norway's major exports in 1981 (2).

Overview

Norway has two statutes relating to the notification of chemicals. In 1976 the Product Control Act was passed (3). This is a simple but comprehensive Act concerning raw materials and products in general. It is an "enabling Act", allowing for numerous regulations to be issued pursuant to it. The other statute is the Worker Protection and the Working Environment Act of 1977 (4). A full English version of this Act was not available at the time of writing.

The details of the notification system under the Worker Protection Act were issued as the Text of October 7, 1977 (5).

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(1) Encycl. Brit. 13 : 269 (1974).

(2) Encycl. Brit. (1983).

(3) The Product Control Act of June 11, 1976, No. 79.

(4) The Worker Protection and the Working Environment Act of February 4, 1977, Norsk Lovtidend, Part I, February 14, 1977, No. 4, pp. 77-108; as amended by Law No. 52 of June 3, 1977, Norsk Lovtidend, Part I, June 16, 1977, No. 17, pp. 465-490 and by Law No. 32 of May 26, 1978, Norsk Lovtidend, Part I, June 16, 1977, No. 16, p. 336. A condensed version has been published in Int'l Dig. of Health Leg. 30 : 109-111. See also ILO Legislative Series 1978, No. I and ILO Social and Labour Bull., 1977, No. 3, pp. 233-237.

(5) Text of October 7, 1977, Norsk Lovtidend, Part I, October 24, 1977, No. 30, p. 847. Noted at Int'l Dig. of Health Leg. 30 : 111 (1979).

In 1982 Regulation No. 1635 was issued pursuant to both the Product Control Act and the Worker Protection Act (6). The Text of 1977 was amended to conform with Regulation No. 1635 (7).

The central elements of the Norwegian system are a classification scheme, a Product Register and a permit scheme. Manufacturers and importers are required to obtain such knowledge as necessary to determine the harmful effects of a substance and are responsible for determining the classification of the substance as it is listed in the Product Registry. Notification is required for the more hazardous categories of substances.

Status of Legislation

The Product Control Act was to enter into force at a later date to be determined (8). The exact date is unknown, but it must be assumed that it was declared in force as Regulation No. 1635 were issued pursuant to it. Most of the provisions of the latter regulation are concerned with packaging, labelling and classifying rather than with notification. Various portions of the regulations were to come into force at different times.

Purpose or Scope of the Legislation

The purpose of the Product Control Act is to prevent products from causing damage to health, or disturbance to the environment by pollution, waste, noise and similar nuisances (9). One objective of the Worker Protection Act is obviously the protection of health in the working environment (10).

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(6) Regulation No. 1635 Concerning Labelling, Sale, Etc. of Chemical Substances and Products Which May Involve a Hazard to Health, Royal Decree of November 26, 1982. Published in condensed form in Int'l Dig. of Health Leg. 34 : 320-321 (1983) and in summary form or in IRPTC Bull. 5 : 29 (1982).

(7) Amendments No. 1428 of September 1, 1982, Norsk Lovtidend, Part I, October 14, 1982, No. 21, pp. 495-496. Noted in Int'l Dig. of Health Leg. 34 : 320 (1983).

(8) Section 16 - Act.

Effective Date of Notification Requirement

While Regulation No. 1635 came into force on March 1, 1983, the provisions relating to notification by manufacturers and importers were to come into force at a date to be set by the Ministry of Environment (11). It is not known if, or when, the notification provisions came into effect.

Type of Notification

Regulation No. 1635 has a special notification requirement for suspected carcinogens. Such substances must be notified to the State Pollution Control Authority by the manufacturer or producer (12). This applies to new substances or those which are in existence.

Generally, however, notification must be given for the manufacture or import of the more hazardous substances (13). A separate notification is required for sale of such substances by wholesalers (14). The Regulations provide that detailed rules for carrying out the notification will be issued (15).

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(9) Section 1 - Act.

(10) As a full version of this Act is not readily available, the review will cover the Products Control Act and Regulation No. 1635.

(11) Section 30 - Regulations.

(12) Section 6 - Regulations.

(13) Section 18 - Regulations.

(14) Section 19 - Regulations.

(15) It is not known if they have been issued.

Notification Time Period

Regulation No. 1635 does not specify when the notification is to be given. It is not specifically stated that notification must be given before manufacture, etc. The provision for sale notification is clearly an ongoing notification as the provision states that a new notification shall be submitted every two years (16).

Indirectly, it is clearly a pre-manufacturing and pre-importing scheme as the Regulation states that manufacturing or importing cannot begin until a receipt for the notification has been obtained from the Products Register (17).

Responsibility for Notification

Manufacturers, importers and wholesalers are responsible for notification (18).

Notification Authority

Manufacturers and importers of suspected carcinogens and wholesalers of the more hazardous substances must notify the State Pollution Control Authority (19). Generally, manufacturers and importers submit notifications to the Product Register (20). Importers must also show Customs authorities a receipt for the notification they have submitted to Product Register (21).

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(16) Section 19 - Regulations.

(17) Section 18 - Regulations.

(18) Sections 6, 16 and 19 - Regulations.

(19) Sections 6 and 19 - Regulations.

(20) Section 18 - Regulations.

(21) Ibid. This, of course, implies that notification is given before importing otherwise how would an importer have a receipt.

Chemicals to be Notified

Generally, notification is required for very toxic, toxic or carcinogenic substances and products. "Substance" means an element (pure chemical basic substance) or a chemical compound of two or more elements. "Product" means a mixture of two or more substances (22).

Therefore, all chemicals do not have to be notified; only the more hazardous ones. The scheme does not distinguish between "new" or existing substances. The State Pollution Control Authority, in consultation with the Directorate for Labour Inspection, has issued a List of Substances. This List classifies substances as very toxic, toxic, harmful, corrosive, irritant, allergenic and carcinogenic (23).

Manufacturers and importers are required to classify substances by comparing the properties of their substances with those of the classified substances on the List. They are required to obtain such knowledge as necessary in order to do so (24). If they determine that the classification of their substance falls within the subset of "very toxic" and "toxic" and if they suspect it is carcinogenic, then it is a notifiable substance.

There is an interesting and unusual mechanism given in Regulation No. 1635 for determining what classification a product shall have. This mechanism involves assigning numerical values to the degree of hazard of the constituent substances on a weight per cent basis (25).

Substances and products which are expressly excluded from the application of Regulation No. 1635 are as follows (26):

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(22) Section 2 - Regulations.

(23) Section 5 - Regulations.

(24) Sections 3 and 5 - Regulations.

(25) Section 7 - Regulations.

(26) Section 1 - Regulations.

(a) solid, manufactured articles (with some exceptions);
(b) alcoholic beverages;
(c) food;
(d) pesticides;
(e) medicines;
(f) tobacco products;
(g) animal feedstuffs.

Exemptions

The Products Control Act provides that regulations or case-by-case decisions may be made to exempt products or persons (27). Regulation No. 1635 does not list exemptions but provides that the Board of the Product Register may, in special cases, grant total or partial exemption from the notification requirement (28).

Notification is not required (other than for suspected carcinogens and the wholesaler notification) if the quantity of the hazardous substance or product is less than 100 kg per year (29).

Inventory

The List of Substance is the Norwegian inventory. It serves as a model for manufacturers and importers to classify their substances while making a binding classification of those substances on the List. The classification of a substance or product determines whether it is notifiable, not the existence of the substance on the List. Presumably new substances are entered on the List as they are notified but the mechanism for entry is not clear from Regulation No. 1635 itself.

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(27) Section 2 - Act.

(28) Section 18 - Regulations.

(29) Ibid.

Content of Notification

The general notification provisions in Regulation No. 1635 require that the following be submitted to the Product Register (30):

(a) name and address of the notifier;

(b) trade name of the substance or product;

(c) the unambiguous chemical specification and identification number of the substance, or the unambiguous chemical specification, identification number and quantity of all the substances of which the product is composed, such that the involved components may be summated to 100 weight percent;

(d) the classification of the substance or product;

(e) the total quantity expected to be produced or imported per year, stated in intervals of 0.1-1 tonnes, 1-10 tonnes, 10-100 tonnes, etc.;

(f) the area of use of the substance or product;

(g) the name of the person possessing the required education or experience to handle hazardous substances.

Testing Requirements

There are no specific testing requirements set out in the Norwegian legislation. As mentioned, manufacturers and importers have a general duty to obtain such knowledge as is necessary in order to determine the classification of a substance. One must obviously do toxicity tests for a new substance in order to determine its toxic properties. The Products Control Act does provide for requests to be made for studies but Regulation No. 1635 does not specify them (31). Perhaps other regulations will be issued.

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(30) Ibid.

Mutual Acceptance of Data

There is no provision in the Norwegian legislation for the application of this principle.

Flexibility in Notification Requirements

The notification requirements are simple and straightforward. As mentioned, exemptions may be made on a case-by-case basis. There is flexibility built into the entire system in the sense that specific tests are not required.

Further Testing Requirements/Follow-Up Measures

Whether or not a notification has previously been submitted, a manufacturer or importer must notify the competent authority if the quantity, area of use or composition of a substance or product is substantially altered (32).

As mentioned, wholesalers must submit a notification every two years.

The Products Control Act has general provisions providing that unspecified information may be required and that samples must be submitted if requested. The Act also provides that the government may initiate tests at the expense of the manufacturer or importer (33).

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(31) Section 5 - Act.

(32) Section 18 - Regulations.

(33) Section 5 - Act.

Special Orders

Other than what has been mentioned, there is little else in the way of expressly stated powers to make special orders. The Act does provide that the government can impose temporary bans on the manufacture, importation, sale, use or other handling of products until sufficient information has been submitted (34).

Protection of Confidential Data

The Products Control Act expressly provides that data submitted to the government is to be kept confidential (35). Notifiers do not have to request or justify confidentiality, nor is there a list of non-confidential data. However, there is a general statement that confidentiality shall not hinder the overall objective of the Act, as mentioned above (36).

Disclosure of Data and Proprietary Rights

Other than what has been mentioned supra, there is no provision in the Norwegian legislation for these issues.

Public Participation

There is no provision for public participation in the Norwegian legislation.

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(34) Section 6 - Act.

(35) Section 11 - Act.

(36) Section 11 in reference to Section 1 - Act.

Enforcement and Penalties

Regulation No. 1635 provides (37) that fines may be imposed for violations pursuant to the Worker Protection Act (38) or pursuant to the Products Control Act (39) - but specific fines are not given. The latter Act does provide that imprisonment may also be imposed (40). If a person violates the confidentiality provision with a view to making a profit, imprisonment may be up to 2 years (41).

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(37) Section 27 - Regulations.

(38) Section 78 of that Act.

(39) Section 13 of that Act.

(40) Section 12 - Act.

(41) Ibid.

3.8 PORTUGAL

Portugal is a member of the OECD. It is also a prospective member of the EEC; the target date for membership is 1986. At that time Portugal will be required to have in place national legislation implementing various EEC Directives concerning environmental legislation.

Recently, Portugal was granted certain temporary exemptions from such requirements. While the Sixth Amendment was not listed in a report on the matter (1) as one of the Directives which Portugal will have an extension to implement, it was indicated that some preparatory work on new chemical notification is going on. Apparently in March of 1983 Portugal submitted a list of all chemicals on its domestic market for the purpose of inclusion in the EEC inventory of existing chemicals.

An English copy of whatever legislation, if any, regarding notification of chemical substances currently in place in Portugal, is not readily available.

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(1) "Portugal Gets Temporary Exemptions from EEC Environmental Legislation", (Current) Int'l Env. Rep. 6 : 469 (1983).

3.9 SPAIN

In the last ten years Spain has undergone a historic and politically significant transition to a modern democratic state. It is now a parliamentary monarchy. Since 1978 Spain has acquired a written constitution. The national parliament, the Cortes, is divided between the Congress or lower house and the Senate or upper house. Executive, legislative and judicial branches of government are separate (1).

While Spain is organized into municipalities and provinces, the country appears to be following Belgium's example of developing "communities" each with a defined degree of autonomy, presumably in an attempt to reduce intra-national cultural conflict. It is not clear from the information readily available what effect this decentralization will have on matters such as environmental legislation.

Negotiations have been going on for several years concerning the eventual entry by Spain into the EEC (2). As in the case of Portugal, which is expected to become a member in 1986, Spain will be required to implement the Sixth Amendment. Portugal has already been granted temporary exemption from the implementation of several environmental Directives? Will Spain be granted similar exemptions?

Information on the status of Spain's efforts to prepare a notification system, if any, is not readily available. Spain has recently implemented legislation for the regulation, supervision and inspection of installations where chemical substances are stored, handled and transferred (3).

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(1) Price Waterhouse, Doing Business in Spain (1983).

(2) Price Waterhouse, Doing Business in the European Communities (1978).

(3) IRPTC Bull. 5 : 35 (1983); Int'l Dig. of Health Leg. 33 : 324-326 (1982).

3.10 SWEDEN

Sweden is a unitary, not a federal state. It is a monarchy although, as in the case of most twentieth century monarchies, power resides with elected representatives. Sweden has a unicameral Parliament (Riksdag) and a Prime Minister with a Cabinet of ministers heading about a dozen government departments. Legislation is often proposed by parliamentary committees. Power to enact laws is jointly vested in the Riksdag and the King in Council (Cabinet). Ordinances and regulations are often instituted by the King in Council alone (1).

The national government has 24 county administrations. In addition there are 23 county councils elected locally (2).

While Sweden has often been referred to as a socialist state this has largely been due to its extensive social welfare system. Most of the western democracies today have similar systems. The Swedish government does not interfere in the economy in a significantly different way or extent than the Canadian government does.

In 1981 chemicals constituted 5% of Sweden's major exports (3).

Overview

Sweden has passed legislation for the control of chemical substances and products. The Act on Products Hazardous to Health and to the Environment (4), passed in 1973, sets out general duties of those in the chemical trade. Such persons must take such steps and observe such precautions as are needed to prevent or counteract injury arising from their products. The authorities have broad powers to intervene if there is a suspicion that a chemical product may be harmful to human health or the environment. The Act gives authority to make regulations requiring information to be submitted to the government. The government authority supervising the Act is to have the power to issue rulings on whether a substance is hazardous. Persons involved in the chemical industry are also under a general duty to be aware of the harmful properties of their chemical properties.

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(1) Encycl. Brit. 17 : 850-851 (1974); Price Waterhouse, Doing Business in Sweden (1980).

(2) Encycl. Brit. 17 : 850-851 (1974).

(3) Encycl. Brit. (1983).

(4) Enacted April 27, 1973. Swedish Code of Statutes 1973 : 329. (Svensk forfattningssamling, June 5, 1973, 4pp). The Swedish government published a booklet containing the Act along with a commentary. A condensed version of the Act appears in Int'l Dig. of Health Leg. 25 : 609-610 (1974).

The Act was amended in 1975 (5) to enlarge the power to require notification of activities involving hazardous substances. As well, a number of Ordinances have been issued setting out requirements for declarations and notifications in certain circumstances.

Generally, the Swedish system is not a notification scheme for new industrial chemicals but a method of regulating identified hazardous substances. Indirectly the legislation forces manufacturers and importers to investigate the hazardous properties of their products, but only in certain circumstances is information required to be submitted.

In February of 1983 the Minister of Agriculture issued terms of reference for a Commission to investigate improved control over the handling of chemical substances and products (6). These wide-ranging terms of reference included a request that the Commission investigate the possibility of a new chemical notification scheme (7):

> Forms of advance-control of chemical substances should be examined by the Commission. Advance-control in this context means that new substances may not be marketed or used unless the responsible controlling authority has been able to assess them. One of the biggest problems connected with the handling of chemicals is the

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(5) Law No. 340 of May 22, 1975, Svensk forfattningssamling, 1975, Vol. 2, June 17, 1975, 2 pp.; noted in Int'l Dig. of Health Leg. 27 : 854 (1976).

(6) Terms of Reference 1983 : 20 Improved Control Over the Handling of Chemical Substances and Products, Ministry of Agriculture, CK3DIRO 201. IS.

(7) Terms of Reference 1983 : 20, p. 9.

little knowledge we have in many cases, of their effects on man and the environment. Here cooperation with the EEC should be explored.

As yet there is no indication of the findings of the Commission but we may assume that its work is preparatory for a major revision of the Swedish legislation (8).

At the same time as setting out the terms of reference above, the Swedish government authorized the Products Control Board to continue construction of the Products Register by requiring further details relating to toxic and dangerous substances (9). The implication is that the Swedish government is moving in the direction of requiring much more data on substances required to be notified before the Commission's report is completed.

Status of Legislation

At the time the Act was passed in 1973, a major set of regulations was issued, Ordinance on Products Hazardous to Health and the Environment (10). This Ordinance contains some provisions relating to notification. It also authorizes (11) the Products Control Board to issue further regulations detailing information to be notified under the Act (12). The

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(8) The Swedish Plastics and Chemicals Suppliers Association, PKL, is publishing a brochure "Marketing of Chemicals and Plastics in Sweden" which will comment on a new Ordinance, not yet published, which will require a form with the acronym "MSDS" to be supplied to buyers of poisonous/hazardous products. A rough translation of an available form indicates that it is similar to the "hazard sheets" used in occupational health and safety. It contains information on the composition of the product, physico-chemical properties, biological properties, labelling, health risk, precautionary measures and first aid.

(9) Government Decision 25, 1983-02-10, Continued Construction of the Products Register, Ministry of Agriculture.

(10) Enacted April 27, 1973. Swedish Code of Statues 1973 : 334. (Svensk forfattningssamling, June 5, 1973, 11 pp.). A condensed version of the Ordinance appears in Int'l Dig. of Health Leg. 25 : 610-612 (1974). It is also contained as an Appendix in the booklet referred to in footnote (4).

(11) Section 54 - Ordinance 334.

(12) Sections 8 and 9 - Act 329.

Products Control Board issued Ordinance Giving Directions on the Reporting of Certain Products on December 23, 1977 (13). This Ordinance requires manufacturers and importers to submit limited information to the Products Control Board. Shortly thereafter, Ordinance With Respect to Product Notification (14) was issued which replaced the December 23, 1977 Ordinance. At the same time a second set of regulations was issued, Ordinance With Respect to Declarations of Certain Products (15). Both notifications and declarations are in respect of specified chemical substances listed in annexes to the Ordinances. The information to be submitted under both is minimal. The declaration is a "second stage" submission requiring marginally more information than the notification.

As mentioned (16), the 1973 Act was amended in 1975 so as to authorize the requiring of data such as the nature, composition and quantity of the substance notified.

Purpose or Scope of the Legislation

The 1973 Act is aimed at the protection of public health and the environment from hazardous substances and preparations as well as products containing hazardous substances and preparations (17). The Act is similar in many respects to toxic chemical trade legislation in Switzerland and New Zealand. The Act provides for a permit system to be established. The main Ordinance under the Act (18) has separate sections on pesticides and PCB products.

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(13) Order No. 2 (PK No. 4) of December 23, 1977, Statens naturvardsverks forfattningssamling, 1978, January 16, 1978, 2 pp. A condensed version appears in Int'l Dig. of Health Leg. 30 : 316 (1979).

(14) Ordinance With Respect to Product Notification, SNFS 1979 : 2, PK : 7, published on July 16, 1979.

(15) Ordinance With Respect to Declarations of Certain Products, SNFS 1979 : 3, PK : 8, published on July 16, 1979. Both SNFS 1979 : 2 and SNFS 1979 : 3 are noted in IRPTC Bull. 3 : 22 (1980).

(16) See footnote (5).

(17) Section I - Act.

(18) See footnote (10).

Effective Date of Notification Requirement

The main Ordinance (1973 : 334) came into effect on July 1, 1973 (19). However, the Ordinance provided that further regulations be made regarding notification (20). Such regulations, SNFS 1978 : 2, came into force on January 30, 1978. Those regulations provided that notification be made for existing chemical products by February 28, 1978 (21). However, the Ordinance which superseded those regulations required notification be made by February 28, 1980 (22). The companion Ordinance required declarations to be made by October 31, 1979, but in the case of a chemical product notified after October 31, 1979, a declaration must be submitted by February 28, 1980 (23).

Type of Notification

The Act requires that anyone who, for commercial purposes, handles or imports chemical products must submit certain information to the competent authority (24). "Handling" means (25):

- manufacture;
- processing;
- treatment;
- packaging;
- storage;
- transportation;
- use;

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(19) Subsection 65(1) - Ordinance 334.

(20) Section 54 - Ordinance 334.

(21) Section 3 - Ordinance SNFS 1978 : 2.

(22) Section 3 - Ordinance SNFS 1979 : 2.

(23) Section 3 - Ordinance SNFS 1979 : 3.

(24) Sections 8 and 9 - Act.

(25) Section 2 - Act.

- collection;
- destruction;
- conversion;
- offering for sale;
- transfer;
- other comparable proceedings.

In practical terms, a notification system based on such a definition of "handling" would probably be unwieldy. The Ordinances setting out the actual data submission requirements refer only to those who produce or import chemical products (26). "Production" means manufacture, purification and other processing (27). Notification may therefore be referred to as pre-manufacturing and pre-importing notification.

There are separate, more general notification provisions in the main Ordinance 334 which state that notification must be given to the Industrial Safety Inspectorate if a person proposes to:

a) manufacture dangerous substances commercially (28);
b) trade in dangerous substances (29);
c) use poisons commercially (30).

Under Ordinance 334 permits are required to manufacture, import or trade in poisons (31).

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(26) Section 3 - Ordinance SNFS 1979 : 2. A product declaration is submitted by the same person who submits a notification: Section 3 - Ordinance SNFS 1979 : 3.

(27) Section 2 - Ordinance SNFS 1979 : 2.

(28) Section 8 - Ordinance 334.

(29) Section 14 - Ordinance 334.

(30) Section 16 - Ordinance 334.

(31) Sections 6, 9 and 12 - Ordinance 334.

Notification Time Period

The general notification provisions in Ordinance 334 do not specify a particular time period but state that notification is due when a person proposes to manufacture or trade in dangerous substances or use poisons.

The information to be provided to the Products Control Board was to be submitted before February 28, 1980. As mentioned above the Products Register is to be expanded. It is not known if there are subsequent regulations specifying a subsequent date.

Responsibility for Notification

Persons who manufacture or trade in dangerous substances or use poisons must submit information under Ordinance 334. Those who produce or import hazardous products are required to submit the notification and declaration referred to in Ordinances SNFS 1979 : 2 and SNFS 1979 : 3 respectively.

Notification Authority

Under Ordinance 334 information is submitted to the Industrial Safety Inspectorate (32). The Products Control Board is responsible for the implementation of the 1973 Act but the day-to-day supervision of the notification requirements was delegated to the Industrial Safety Inspectorate, which is subordinate to the Board of Industrial Safety.

The information supplied under Ordinances SNFS 1979 : 2 and SNFS 1973 : 3 was to be provided to the Products Control Board directly (33).

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(32) Sections 8, 14 and 16 - Ordinance 334.

(33) Section 3 - Ordinance SNFS 1979 : 2 and Section 3 - Ordinance SNFS 1979 : 3.

Chemicals to be Notified

The 1973 Act does not apply to (34):

- foodstuffs;
- pharmaceuticals;
- animal feeds;
- radioactive substances;
- flammable or explosive products which have no other hazardous properties.

Ordinance 334 does not apply to tobacco or to alcohol (unless the hazard is the result of some constituent other than ethanol) (35). There are special provisions in Ordinance 334 which apply to pesticides generally and to PCB products specifically; these will not be reviewed herein.

The 1973 Act generally covers products hazardous to health and to the environment, meaning any substance or preparation which, by reason of its chemical or physico-chemical properties or handling, is liable to cause harm to humans or the environment and any product containing such substances or preparations if the product is liable to cause such harm (36).

Ordinance 334 subclassifies products hazardous to health and to the environment, if they are liable to cause harm to man, as poisons or dangerous substances. The poison classification includes substances used mainly in the production of pharmaceuticals and that the National Board of Health and Welfare has designated as poisons and other substances whose handling is associated with very grave hazards to health. "Other substances under the main heading are classified as dangerous substances" (37). Preparations are included in the definitions of poison or dangerous substance if the preparation is hazardous solely due to the inclusion of a poison or dangerous substance (38). The Products Control Board may, if human health risks necessitate, direct that products be regulated as if they were poisons or dangerous substances (39).

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(34) Section 3 - Act.

(35) Section 49 - Ordinance 334.

(36) Section 1 - Ordinance 334.

(37) Section 2 - Ordinance 334.

Ordinance SNFS 1979 : 2 requires notification for a specified list of chemical products derived from the Swedish Customs Tariff 1977 : 975. A 38 page list is attached to the Ordinance. Many of the items are listed generically so that the actual number of discrete chemical substances involved is extensive. Since these chemical substances are already listed in the Customs Tariff they are not "new" chemicals. Note that despite the use of the Customs Tariff list, the notification is for substances manufactured in Sweden which would be named on the list if they were imported, as well as imported substances.

Ordinance SNFS 1979 : 3 requires a declaration to be submitted with respect to chemical products appearing on a list attached to the Ordinance. This 16 page list is also derived from the Customs Tariff and appears to be a sub-set of the list attached to Ordinance SNFS 1979 : 2. Again the chemicals involved are not "new".

The chemicals to be notified pursuant to Ordinance 334 are also not "new" in the sense that they must be classified as "poisons" or "dangerous substances". The Products Control Board has a duty to publish reference schedules listing poisons and dangerous substances (40).

How are "new" chemicals dealt with? The Swedish legislation does not expressly contemplate notification of "new" chemicals. Because of the general duty to be knowledgeable about the harmful properties of a chemical manufactured or imported (41), and keeping in mind that the government may intervene on a suspicion that a substance is harmful, a manufacturer or importer is indirectly motivated by the Act to determine the classification of a new chemical. At the request of the party concerned, the Products

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(38) Section 3 - Ordinance 334.

(39) Section 4 - Ordinance 334.

(40) Section 5 - Ordinance 334.

(41) Section 5 - Act.

Control Board shall issue a ruling as to whether a chemical product is hazardous to health (42). The Board may (in distinction to "shall") issue a ruling as to whether the chemical is hazardous to the environment. An investigation by the Board is to be paid for by the person requesting the ruling (43).

Exemptions

The Act allows exemptions to be granted from the application of the Act in the case of some particular kind of product or some particular form of handling or importation (44). Specifically the Products Control Board is empowered to exempt a preparation, classified as a poison or dangerous substance from the application of Ordinance 334 (45).

Ordinance 334 notification requirements do not apply to the packing or repacking of a dangerous substance (46), or when a dangerous substance is offered for sale in the closed original package in which the product was acquired (47).

Notification is not required for the commercial use of poisons if (48):

(a) the poison is used only occasionally or in extremely small quantities;

(b) the poison is used in research or educational laboratories; or

(c) medical analysis operations.

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(42) Section 55 - Ordinance 334.

(43) Ibid.

(44) Section 4 - Act.

(45) Section 3 - Ordinance 334.

(46) Section 8 - Ordinance 334.

(47) Section 14 - Ordinance 334.

(48) Section 16 - Ordinance 334.

Under Ordinance SNFS 1979 : 2, notification is not required for chemical products if the annual production or importation is less than 100 kg (49). A person subject to this exemption would not have to submit a declaration under Ordinance SNFS 1979 : 3 as "a product declaration shall be submitted by the person notifying the product" (50).

Inventory

Substances requiring notification under Ordinance 334 are either poisons or dangerous substances. If a hazardous substance is not a poison, it is a dangerous substance. Despite the latter definition by default, the Products Control Board has a duty to publish reference schedules listing poisons and dangerous substances (51). Existing poisons and dangerous substance, once on the lists, would require notification under Ordinance 334.

It may be that there are further regulations in existence specifically authorizing the establishment of a Products Register as other sources indicate that the information required by Ordinances SNFS 1979 : 2 and SNFS 1979 : 3 enters such a Products Register. According to one of these sources (52), by 1980 100,000 products were notified by 2,500 companies under Ordinance SNFS 1979 : 2. About 15,000 substances were declared by about 900 companies under Ordinance SNFS 1979 : 3. Chemical substances on each of these two lists requires notification.

Content of Notification

A general provision in the Act states that, if prescribed, persons handling or importing any substance, preparation or other product must furnish "all information on the composition , other properties and handling of the product that is necessary for assessing the danger it presents to public health or the environment" (53). There is no indication that regulations have been made which require the submission of "all information", or anything close to it.

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(49) Section 3 - Ordinance SNFS 1979 : 2.

(50) Section 3 - Ordinance SNFS 1979 : 3.

(51) Section 5 - Ordinance 334.

(52) IRPTC Bull. 3 : 22 (1980).

A second provision in the Act specifically authorizes regulations requiring the filing of a notification, but the original provision doesn't indicate what information should be in such a notification (54). As mentioned, supra, that particular provision was amended in 1975 (55) to require that anyone who for commercial purposes handles or imports any products hazardous to health and to the environment shall annually supply details of the nature, composition, and quantity of the products, and of the type of dealings involved (56).

The notification requirements under Ordinance 334 for poisons and dangerous substances do not specify what information is contained in such notifications. The Industrial Safety Inspectorate is required to confirm that it has received the notification (57).

Notification under Ordinance SNFS 1979 : 2 requires the following information (58):

(a) the name or trade name of the person submitting information including the national registration or organization number;

(b) the address and telephone number of the person submitting information;

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(53) Section 8 - Act.

(54) Section 9 - Act.

(55) See footnote (5).

(56) The version of this amendment readily available is a condensed version. Given the original wording of section 9 of the Act, in that it stated that the public authority administering the Act has the power to order notification, it is not clear that this amendment empowers the authority to request this information or directly requires persons to submit the information.

(57) Section 16 - Ordinance 334.

(58) Section 4 - Ordinance SNFS 1979 : 2.

(c) the trade nume of the product, or if this does not exist, its trade description or trade designation. If there is more than one name, each are to be indicated;

(d) the number of the product according to the Customs Tariff 1977 : 975;

(e) indication as to whether the person submitting information has produced or imported the product or given the product a new trade name or new trade description or trade designation.

This is certainly a minimal amount of information, but then we do not know the specific purpose of the Product Register. The Products Control Board assigns the notified product a notification number (59).

More information is required for the designated chemical substances under the declaration provision of Ordinance SNFS 1979 : 3 (60):

(a) the trade name of the product or, if this does not exist, its trade description or trade designation;

(b) the notification number of the product;

(c) the chemical composition of the product with particulars regarding such impurities as can be of significance in the evaluation of the health and environmental hazards of the product and under all circumstances impurities constituting at least 1% of the weight of the product;

(d) explanatory information as to the use of the product and the quantity produced or imported.

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(59) Section 5 - Ordinance SNFS 1979 : 2.

(60) Section 5 - Ordinance SNFS 1979 : 3.

Again, while more information is required under this Ordinance, the quantity and quality of the information is minimal.

Testing Requirements

As mentioned, there is a duty under the Act that anyone manufacturing or importing a product hazardous to health and the environment to "inquire carefully into its composition and other properties with a bearing on public health or environmental protection" (61).

There are no specific testing requirements in the Swedish legislation.

Regulations could be issued under the provision of the Act stating that, if prescribed, all information on the composition, other properties and handling of the product necessary for evaluation must be submitted (62). No such regulations are apparent.

Mutual Acceptance of Data

There is no evidence of the existence of this principle in the Swedish legislation.

Flexibility in Notification Requirements

Since the notification requirements in the Swedish legislation are minimal, provision for the omission or substitution of data was likely considered unnecessary.

Ordinance SNFS 1979 : 3 permits an importer, who cannot provide information concerning the composition of the product, to have another party submit the information. That other party's name must be indicated on the declaration (63).

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(61) Section 5 - Act.

(62) Section 8 - Act.

(63) Section 4 - Ordinance SNFS 1979 : 3.

Further Testing Requirements/Follow-up Measures

There are no further testing requirements in the Swedish legislation. There are provisions not related to notification which involve the issuing of permits and labelling requirements.

The competent authority has the right to receive upon request the information and documents needed for the exercise of supervision pursuant to the Act (64). There is no indication how this broad power has been used.

Special Orders

There are no provisions with respect to special orders relating to notification.

Under Ordinance 334 the Products Control Board may direct that a product hazardous to health and to the environment or a waste derivative of such a product may be destroyed, converted or otherwise dealt with only with the special permission of the Board (65).

Protection of Confidential Data

The 1973 Act provides that any person who learns "occupation secrets or business circumstances" in the course of official duties shall not "improperly disclose or make use of" what he has learned. Violations may result in a fine or imprisonment (66).

The Commission investigating the improvement of the Product Register will be studying the questions of confidentiality, computer security and the legal status of registered information and information supplied from the Register (67).

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(64) Section 12 - Act.

(65) Section 52 - Ordinance 334.

(66) Section 17 - Act.

(67) See footnote (6).

Disclosure of Data and Proprietary Rights

Information is not readily available on the question of disclosure of data. As mentioned it is reasonable to assume that there is an ordinance in existence which specifically established the Products Register. That ordinance might contain disclosure provisions.

The type of information submitted under the Swedish system is not such as to raise a concern about proprietary rights as it is very minimal.

Public Participation

"For the furtherance of the interest of consumers in the area of products hazardous to health and to the environment, an organization that qualifies as a paramount organization under the Right of Association and Negotiation Act (1936 : 506) is entitled to lodge an appeal against a decision made under (the 1973 Act) insofar as this is permissible under regulations promulgated by the King-in-Council" (68). No such regulations are evident.

Enforcement and Penalties

Penalties range from fines to imprisonment for not more than one year for violations of provisions of the Act or regulations, prohibitions or conditions promulgated under the Act. Proceedings under the Criminal Code are contemplated. Violation of regulations made under the Act with respect to importation are punishable under a 1960 Act concerning smuggling (69).

If a person fails to discharge a duty imposed by the Act, regulations or an order, the authorities may direct that rectification be made at that person's expense (70).

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(68) Section 19 - Act.

(69) Section 16 - Act.

(70) Section 13 - Act.

3.11 SWITZERLAND

The Swiss Confederation consists of a federation of twenty-six Cantons. In all matters not specifically reserved to the Confederation under the country's federal constitution, such as foreign affairs, defense, communications and some fields of political economy, the Cantons can legislate autonomously. Thus, there is a two-level system of legislation (federal and cantonal). In the legislative process, the opposition is made up of the people at large who, under a system of referendum, can accept or reject legislative measures. Not surprisingly, this can slow down the legislative process considerably although the system likely results in a higher level of consensus. The three major language groups in Switzerland are German (65%), French (18%) and Italian (12%) (1).

Switzerland has a political tradition of neutrality. It is not a member of the EEC, but being land-locked in the midst of various Member States, one might expect the country to follow closely efforts at harmonization of trade laws among neighbours. Yet while Switzerland has recently enacted comprehensive environmental protection legislation (2), the latter does not appear to change the Federal Law on Trade in Toxic Substances (3), known as the Toxicity Law in its substantive provisions.

The Toxicity Law is federal legislation. Notification of toxic substances is to a federal office. The Swiss Federal Council, has a variety of rule-making powers under the Law, but many provisions of the Law require implementation, monitoring and enforcement by the Cantons and in this regard the Federal authorities have a responsibility to "exercise general supervision of the implementation of (the) law by the cantons and may issue the cantons with relevant instructions" (4). With exceptions having to do with the evaluation of toxic substances, maintenance of the List of Toxic Substances, issuance of certain permits, import of toxic substances, the implementation of the Toxicity Law rests with the Cantons (5).

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(1) Price Waterhouse, Doing Business in Switzerland (1982).

(2) Law on the Protection of the Environment of October 7, 1983.

(3) March 21, 1969.

(4) Article 22 - Law of March 21, 1969.

(5) Article 21, para. 1 - Law.

Overview

The Toxicity Law predates the Sixth Amendment, the American TSCA and the Japanese Chemical Substances Control Law. It provides that any toxic substance entering the Swiss market must first be reported to the government for classification on an official list of toxic substances. Apparently, a "new" but "non-toxic" substance need not be notified. Evaluation is based largely on toxicological data supplied by the manufacturer or importer. Class One contains the most dangerous substances and Class Five contains the least dangerous. Conditions of use are based on a substance's class. The scheme covers chemical products. Existing chemical products must also have a designated class. With some exceptions, permits must be obtained before a person can trade in toxic substances.

Status of Legislation

The Toxicity Law has been in effect for twelve years. There has been little published in the international literature on the operation of this law (6). A new law on the protection of the environment was passed in 1983. It did not substantially affect the Toxicity Law.

The only readily available Order issued pursuant to the Toxicity Law which is relevant is the Implementing Order of December 23, 1971 which dealt with the form and content of the toxic substances list, the notification requirements and, more extensively, the conditions under which different classes of toxic substances may be used.

Purpose or Scope of the Legislation

The primary purpose of the Toxicity Law appears to be the protection of human health and life (7). However, there are provisions directing "owners" of toxic substances to take appropriate measures to prevent pollution (8) and requiring employers to take measures to prevent poisoning of employees although the provision is without prejudice to existing labour legislation (9).

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(6) The Ordinance of July 31, 1979 On the Distinctive Marking of Laboratory Chemicals, Recueil des lois federales, October 23, 1979, No. 42, pp. 1360-1364, was noted in Int'l Dig. of Health Leg. 32 : 292 (1981).

(7) Article 14 - Law.

Effective Date of Notification Requirement

The Toxicity Law was enacted in 1969 but did not come into effect until 1972. In December of 1971 the Order implementing the Law was passed; it did not come into force until April 1, 1972 (10).

The Order states that toxic products not on the List of Toxic Substances must be declared to the Health Office by October 1, 1972 (11). Persons intending to trade in toxic substances must apply for a permit from the competent cantonal authority by April 1, 1973 (12).

Type of Notification

A toxic substance may not be marketed in Switzerland until it has been included in the List of Toxic Substances (13). In order to be placed on the list the intention to market must be declared to the federal government (14). Thus, the Swiss system can be considered to require pre-marketing notification.

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(8) Article 16 - Law.

(9) Article 17 - Law.

(10) Article 92 - Order of December 21, 1971.

(11) Article 89, para. 2 - Order.

(12) Article 89, para. 3 - Order.

(13) Article 5 - Law.

(14) Article 6 - Law.

However, "marketing" is defined as "the initial manufacture or import and initial recommendation or offer for the purpose of sale in Switzerland" (15). Is this to be read conjunctively? In other words, is manufacture or import alone not marketing, but if there is, in addition, an offer for the purpose of sale, the manufacture or import becomes "marketing". Without assurance of correct translation from the official German version and without knowledge of specific Swiss rules for statutory interpretation, it is difficult to be sure.

It might be safe to say that the Swiss system is a pre-manufacture and pre-import notification scheme, keeping in mind that there must be a commercial context. This view is assisted by the provision (16) that "toxic substances approved for trade will be entered in a List of Toxic Substances ...". "Trade" is defined as "manufacture, processing, storing, use, import, sale, purchase, recommendation, offering for sale or disposal" (17).

Transport within, transit through and export from Switzerland are not deemed to be "trade" (18).

It should be noted that the Toxicity Law is primarily concerned with control through registration and the issuance of use permits. The critical step is receipt of a permit. The system might be called a pre-permit notification system.

Notification Time Period

There does not appear to be a notification time period in the Swiss law similar, for example, to the 45 day period in the Sixth Amendment. A toxic substance may not be marketed until it has been included in the List of Toxic Substances (19). Even then a permit must be obtained before trade can commence (20). The Swiss system is not one where there is an automatic right to commence marketing unless the government disapproves, as is the case in many other countries. Rather, explicit permission to market must be given.

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(15) Article 3, para. 2 - Law.

(16) Article 4, para. 1 - Law.

(17) Article 3, para. 1 - Law.

(18) Article 3, para. 3 - Law.

(19) Article 5 - Law.

The government cannot delay indefinitely, however. If chemical products are intended for public use, the notification authority must decide within two months (of what is not clearly stated in the Law) whether a chemical product will be included in the List (and therefore eligible for a use permit) (21). There does not appear to be any time period applicable to products for non-public use. Further, once on the List, there does not appear to be a time period for issuance of a use permit.

Responsibility for Notification

The Toxicity Law states that "persons intending to market a toxic substance" must declare this to the federal government (22). As mentioned, "marketing" includes initial manufacture or import. Therefore responsibility for the notification would rest with manufacturers, importers and those who recommend or offer for the purpose of sale (but note the above-mentioned difficulty of reading this conjunctively or disjunctively).

Significantly, the implementing Order states that "the declarer must be domiciled in Switzerland" (23). The term "domicile" has important legal implications as discussed in the chapter supra on Germany. This requirement necessitates the use of a Swiss representative or agent during the notification process - not a Swiss resident, but a Swiss national.

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(20) Article 7, para. 1 - Law.

(21) Article 25, para. 3 - Law.

(22) Article 6, para. 1 - Law.

(23) Article 17, para. 2 - Order.

Notification Authority

Notification must be made to the Federal Office of Health (24). It is the Federal Ministry of the Interior which is required to establish a Specialist Committee, which is the entity responsible for evaluating and classification of toxic substances (25).

The Federal Office of Health maintains the List of Toxic Substances and issues some types of permits (26). Normally substances or products are placed on the List on the basis of advice provided by the Specialist Committee (27), but in the case of priority "public use products", and where there is little doubt, a decision may be made without the opinion of the Specialist Committee (28). But it is up to the Federal Council to decide which substances or products are products for public use (29).

Chemicals to be Notified

The Toxicity Law does not apply to:

- radioactive substances (30);
- pharmaceutical products covered by Federal and Canton regulations (31);

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(24) Article 6, para. 1 - Law.

(25) Article 24 - Law. The Specialist Committee consists of representatives of the competent Federal and cantonal authorities, the Swiss Accident Insurance Institute and scientists.

(26) Article 25, para. 1 - Law.

(27) Article 25, para. 2 - Law.

(28) Article 25, para. 3 - Law.

(29) Article 25, para. 4 - Law. The Order defines "products for public use" as substances and products for general use or which can be sold to anyone - Article 5.

(30) Article 1, para. 2 - Law.

(31) Article 1, para. 4 - Law; more specifically defined in Article 2 - Order.

- foodstuffs and consumer goods covered by Federal Canton regulations (32).

"Substances" are "base substances" (unmodified natural substances and chemically uniform substances) or simple technical mixtures of substances which have not been prepared with a view to specific applications, provided such substances are marketed under a chemical or trade name (33). "Products" are natural substances modified in composition for a specific use or mixtures of substances or substances made into a specific form (34). "Products for public use" are substances and products for general use or "which can be sold to anyone" (35) and "commercial products" are substances and products which are recommended or sold for commercial or industrial use, provided they are not substances which are marketed under a chemical or trade name (36).

"Toxic substances" are inanimate substances and products made from such substances which on absorption by, or contact with, the body even in relatively small quantities may, by virtue of chemical or physical-chemical processes, endanger the life or health of humans and animals and which therefore need to be handled with particular care (37).

Other than the exceptions discussed infra a "toxic substance" must be entered in the List of Toxic Substances before it can be marketed (38) and intention to market a toxic substance which must be entered in the List must be declared to the Federal Office of Health (39).

The Swiss system is not designed for "new substances" but "toxic substances". A new substance need only be notified if it is "toxic", therefore the above-mentioned definition is critical for the potential notifier. If in doubt, a manufacturer or importer should contact the competent authority on this question (40). The competent authority has the power to procure the documents required if a substance has not been declared and there is reason to suppose that it is a toxic substance (41). This provision may not mean that the government demands the notification material from the manufacturer or notifier because the heading in the Order over this provision states "testing on the initiative of the Health Office".

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(32) Article 1, para. 4 - Law.

(33) Article 3 - Order.

(34) Article 4 - Order.

(35) Article 5 - Order.

(36) Article 6 - Order.

(37) Article 2 - Law.

(38) Article 5 - Law.

(39) Article 6, para. 1 - Law.

Exemptions

The following substances need not be declared for the purpose of being entered on the List of Toxic Substances:

(a) Research exemption - if the substance is used exclusively for research purposes (42).

(b) Chemical production process exemption - if the substance is used as a raw or auxiliary material or intermediate product in chemical production processes (43).

(c) Non-toxic exemption - the Law does not require all new substances to be notified - simply "toxic substances". If a substance is clearly non-toxic, then notification is not necessary.

(d) Made-to-order chemicals - products manufactured for individual purchasers to their specifications and for their own use need not be notified to the competent authority (44).

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(40) Article 20 - Order.

(41) Article 21 - Order.

(42) Article 4, para. 1 - Law.

(43) Article 4, para. 1 - Law. "Chemical production processes" is defined broadly in Article 8 - Order.

(44) Article 17, para. 6 - Order.

If the substance need not be put in the List, it need not be declared to the competent authority. There are other exemptions in the Toxicity Law, but they relate to permits - a step which follows notification. The permit system will not be reviewed in this survey.

Inventory

The core of the Swiss system for regulating toxic substances is the List of Toxic Substances. As mentioned, a toxic substance may not be marketed until it has been included in the List. Obviously a "new" toxic substance will not be on the List. The List is constantly updated as substances are evaluated, classified and placed on the List. The List is in three parts with categories of information under each entered name (45):

(a) list of basic substances
  (i) chemical name;
  (ii) toxicity category;
  (iii) manufacturer (if applicable);
  (iv) special remarks.

(b) list of commercial products
  (i) chemical name or group designation;
  (ii) trade name (if applicable);
  (iii) percent content for components in toxicity categories 1-3;
  (iv) producer, importer, representative or salesman in Switzerland (if applicable);
  (v) toxicity category;
  (vi) Health Office control number (if applicable);
  (vii) special remarks.

(c) list of products for public use
  (i) trade name, fancy name or technical name;

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(45) Article 12, para. 2 - Order.

(ii) percent content for components in toxicity categories 1-3;

(iii) toxicity category;

(iv) Health Office control number;

(v) agricultural research institute control number (if applicable);

(vi) use;

(vii) manufacture, importer, representative or seller in Switzerland;

(viii) special remarks.

"Special remarks" include "conditions for specialist knowledge for handling toxic substances, information on special types of sale, ban on use for specific purposes, warning colour, warning odour, special labelling requirements, etc." (46).

The List is also divided into five Categories with Category 1 containing the most hazardous substances and Category 5 containing the least hazardous substances (47). It is important to note that all substances on the List, regardless of which Category they are in, are "toxic substances". Yet not all toxic substances are on the List; only those approved for trade. The classification of substances into these five categories is to be determined according to "their overall hazard" (48).

Particular conditions on marketing and use follow the classification of substances. A notifier must meet those conditions, which are requirements beyond the necessities of notification.

Content of Notification

The way the Toxicity Law is designed, a person would have to know whether their substance was "toxic" to decide whether or not to notify the competent authority. How would the person know without doing tests? The definition of toxic substance is objective and it is broad. A person could not say five years after marketing ... "we didn't know it was toxic". Unless a substance was virtually inert a person would be taking a large risk by not notifying the competent authority.

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(46) Article 12, para. 3 - Order.

(47) Article 4, para. 2 - Law.

(48) Article 13, para. 1 - Order.

What must a manufacturer or importer do to have a new substance placed on the List, as the first step toward putting the substance into circulation?

A notifier must submit a declaration of the intent to market a toxic substance to the Federal Office of Health (49). The declaration must be accompanied by appropriate test certificates on the toxicity and degree of hazard of the substance or product, and where applicable, a sample of the toxic substance and the documents required to assess which protective measures may be necessary (50).

Apparently there is a standard form for the declaration (51). Samples supplied must be "double samples" in the form and packaging in which they are to be marketed together with any enclosures (52).

The supporting documents must contain the following information (53):

(a) composition;
(b) intended purpose or application;
(c) method of use;
(d) any scientific, test and investigation certificates;
(e) advertising material.

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(49) Article 6, para. 1 - Law.

(50) Article 6, para. 2 - Law.

(51) Article 17, para. 1 - Order.

(52) Article 17, para 3 - Order; unless the content is greater than 2 kg or 2 l, in which case the label and enclosures and a 200 g sample are to be submitted.

(53) Article 18, para. 1 - Order.

Agricultural chemicals and substances intended for use in water require approval of federal agricultural and environmental offices, respectively (54).

Further categories of information are obtained in an indirect manner. The packaging must be supplied with the sample when notified. The Toxicity Law contains provisions requiring the following on labels (55):

(a) the nature of the toxic substance;
(b) the percentage toxic content (depending on the degree of hazard of the toxic substance);
(c) the toxicity Category;
(d) types of uses which are not permitted;
(e) protective measures;
(f) first-aid measures;
(g) the seller, manufacturer or importer.

Testing Requirements

The Swiss legislation is vague and indirect in setting out testing requirements. Certain information is required to be submitted but specific tests are not expressly demanded - but they are implied. A packaging label must be supplied. On it the toxicity category must be noted. A major basis for classification is acute oral LD_{50} values for rats. A value of up to 5 mg/kg indicates category 1, for example. Therefore, a person must do an acute toxicity test in order to submit the substance's packaging.

On the other hand, it appears to be the responsibility of the federal government to evaluate and classify substances submitted to it (56). The federal government is required to establish a Toxicological Documentation Centre (57), which is to be established in the Health

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(54) Article 18, paras. 1 and 2, respectively - Order.

(55) Article 15, para. 2 - Law.

(56) Article 24 - Law; Article 25, para. 2 - Law; Article 18 para. 1 -Order.

(57) Article 18 - Law.

Office (58). The Documentation Centre is to make available to the Specialist Committee the documents it requires to evaluate toxic substances and classify them according to toxicity categories (59). On advice from the Specialist Committee, the Office of Health makes the final decision (60). One provision states that the Federal Ministry of the Interior will determine the fees for testing the toxic substances (61).

This latter point suggests that the government will be doing some testing itself. Frankly, the law is confusing on this issue - nevertheless, some testing must obviously be done by the notifier as "test certificates" must be submitted (62).

What tests are required for the classification of toxic substances? As mentioned, the classification is determined according to "overall hazard". The following contribute to the evaluation (63):

(a) acute oral toxicity test;

(b) sub-acute and chronic toxicity or other effects (eg. carcinogenicity, teratogenicity) if these indicate a much greater or a specific hazard;

(c) danger of poisoning by parental absorption; skin or inhalation;

(d) relevant observations of human beings, in particular infants or pregnant mothers;

(e) increase or reduction in hazard by virtue of special type, form or appearance of the products or packaging or other properties (odour/taste).

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(58) Article 75 - Order.

(59) Article 76, para. 2 - Order.

(60) Article 25, para. 2 - Law.

(61) Article 22 - Order.

(62) Article 6, para. 2 - Law.

(63) Article 13 - Order.

Mutual Acceptance of Data

There is no provision in the Law or implementing Order for the recognition of data or evaluation/approval of notifications made elsewhere.

Flexibility in Notification Requirements

None of the factors determining inclusion of a substance in the List of Toxic Substances may be altered without the approval of the Health Office (64). This implies that some flexibility is available with advance approval. No criteria are indicated.

Indirectly related to flexibility in notification requirements is the provision that detailed label requirements may be "relaxed" by the Federal Council, provided that the protection of life and health is not impaired (65).

Further Testing Requirements/Follow-up Measures

Following the initial submission of data and entry onto the List, a person must normally obtain a permit. There are different categories of permits. The details are too complex to review here. Significantly, the issue of permits is somewhat discretionary in that authorization may be subject to additional conditions. This may mean further information must be submitted and/or conditions on handling or use may be imposed (66).

The provisions in the implementing Order which state that classification will be based on acute oral toxicity tests also contains a statement that in certain cases the Health Office "may order an additional experimental toxicological investigation" (67).

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(64) Article 16, para. 1 - Order.

(65) Article 15, para. 4 - Law.

(66) Article 8, para. 3 - Law; Article 9, para. 2 (a) - Law.

(67) Article 13, para. 4 - Order.

The Health Office may reclassify a toxic substance under certain circumstances (68).

Persons trading in toxic substances, when requested, must provide information as required and must allow the authorities to inspect relevant documents, grant them access and permit them to take samples (69).

Special Orders

The competent authorities have the power to "take what action may be necessary" if a person fails to fulfill obligations under the Law or Order. The person is entitled to a hearing (70).

Protection of Confidential Data

All government entities involved in implementing the legislation are "subject to an obligation to maintain secrecy" (71).

Disclosure of Data and Proprietary Rights

The federal government must support the establishment of Toxicology Information Centres. These Centres are to receive information from the Office of Health on the composition of products, although conditions on the transfer of data are imposed (72). The "secrecy provision" mentioned above does not apply. The conditions which are imposed by the implementing Order relate to provision of data for the prevention or treatment of poisoning by medical officers (73).

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(68) Article 16, para. 3 - Order.

(69) Article 28 - Law.

(70) Article 30 - Law.

(71) Article 29 - Law.

(72) Article 19 - Law.

As mentioned in the section above on "Inventory", certain categories of information are published in the List of Toxic Substances.

A consideration of proprietary rights to data is not explicitly referred to in the Law or Order. Once a substance is on the List a person need only apply for the appropriate permit, if required.

Public Participation

No reference to participation by the public in decision-making is to be found.

Enforcement and Penalties

Many of the provisions of the legislation are enforced by the Cantons. Criminal prosecution is the responsibility of the Cantons (74).

Offences include marketing a toxic substance not yet included in the List of Toxic Substances (75). Other offences are largely concerned with permits. Depending on whether an offense was committed through negligence or with intent, penalties are limited to a fine of 1,000 Francs or imprisonment up to six months and/or a fine up to 20,000 Francs, respectively (76).

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(74) Article 37 - Law.

(75) Article 32, para. 1 - Law.

(76) Articles 32 and 33 - Law.

(73) Articles 77 and 78 - Order.

An interesting provision states that if an offense results in an "unlawful pecuniary advantage" the court must sentence "the culprit to pay an equivalent sum to the State" (77). In other words, if a person sold a toxic substance not on the List and made a profit of $100,000, the convicted person would be required to pay $100,000 to the State.

The Courts are empowered to impound toxic substances under certain circumstances (78).

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(77) Article 35 - Law.

(78) Article 36 - Law.

3.12 TURKEY

Turkey is a republic with a written constitution (1961). The Grand National Assembly has a lower chamber, the National Assembly, and an upper chamber, the Senate. The President, elected by the Grand National Assembly, selects a Prime Minister, who forms a government subject to approval by the National Assembly. During the 1960s the traditional Muslim legal system was replaced by a Western system based on the Swiss civil code, the Italian penal code and German commercial law (1).

Unlike the European countries (including Greece), where chemicals comprise 5-22% of total exports, chemicals are not mentioned in Turkey's major exports of 1981. Turkey's major exports are agricultural (2).

There is no indication in the international literature that Turkey has chemical control legislation of any nature.

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(1) Encycl. Brit. 18 : 790-791 (1974).

(2) Encycl. Brit. (1983).

3.13 UNITED STATES

The United States is a federal state with a written Constitution and a separation of legislative, executive and judicial powers.

As in Canada, the American federal government does not have unlimited powers. Federal environmental regulation must proceed under at least one of a group of specific federal powers. For the purposes of toxic substance control, the most important of these is the power to regulate interstate commerce. The "commerce clause" has, through a number of court decisions, been found to be very broad. In the last 50 years, no congressional statute has been found unconstitutional through a failure to meet the "commerce clause" test (1).

The Environmental Protection Agency (EPA) was created in 1970 to consolidate most of the federal government's environmental regulatory activities in a single agency. The EPA administers the Toxic Substances Control Act (TSCA) (2).

The United States has the most open or "transparent" rule-making processes in the world, be they legislative or administrative. The U.S. has a potent Freedom of Information Act and an enormous lobbying system. There are overt political appointments to the higher levels of bureaucratic agencies (and sometimes middle levels). There is a relatively high level of mobility of administrators between agencies and between the civil service and industry. There are vocal public interest groups and an aggressive news media. Further, the U.S. has a strong legal tradition of judicial review of administrative actions.

As a consequence, the details of the American new chemical control system are a patchwork of compromise. The system also seems to be in a constant state of evolution. The political need to accommodate domestic industry has likely hampered the American ability to cooperate internationally for the harmonization of chemical control laws. The "transparent" nature of the rule-making process has meant, however, that there is voluminous background information available on TSCA and its application (3). This "on-the-record" approach has its advantages, but it is fair to say that it has been an obstacle in the way of informal international negotiations to harmonize chemical control laws.

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(1) Findley and Farber (1983), pp. 165-170.

(2) Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. 2601-2629 (1976)).

Overview

The chief characteristics of the TSCA system are as follows:

a) It requires premanufacture notice for new chemicals as opposed to premarket notice.

b) Notices must be submitted 90-180 days before manufacture as opposed to 45 days before marketing.

c) A minimum set of studies is not required as it is under the Sixth Amendment. The OECD Minimum Pre-Marketing Set of Data is suggested.

d) Development of data is the responsibility of manufacturers and importers.

Perhaps the most significant point is that the U.S. PMN system does not require a notifier to generate information for the purpose of notification as does the European system. The identity of the substance must be given. A notifier must provide all information requested to the extent that it is "known or reasonably ascertainable" by the notifier (4). The phrase is defined (5) to mean "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know".

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(3) Even summaries of telephone calls between EPA staff and outside persons (insofar as they are relevant to rule-making) are a matter of public record (48 FR 21742).

(4) 720.40(d), 48 FR 21747; subsection 5(d)(1)(A), TSCA.

(5) 720.3(p), 48 FR 21744.

What this means is that the specific information required can only be defined on a case-by-case basis. As the EPA has stated (6):

> "The meaning of this phrase will depend on the specific circumstances surrounding the development of the new chemical. The nature of the substance, the projected sales volume and profit, and the size of the company are factors in determining what information can reasonably be obtained ..... data-gathering that is so costly as to preclude commercialization is not reasonable."

Status of Legislation

TSCA was enacted in 1976. In January of 1979 EPA proposed PMN rules and forms to implement the notice requirements in TSCA. EPA began its new chemical notice program on July 1, 1979 on an interim basis (7). Since then EPA has received and reviewed more than 2,500 notices on new substances (8). The final PMN rule and notice form were published May 13, 1983, and were to be effective July 12, 1983 (9). However, the effective date of the PMN rule was extended to October 26, 1983 with several provisions being stayed pending clarification (10).

A bill to amend TSCA was introduced to the House of Representatives on November 3, 1983. The amendments would include testing and notification requirements for new chemicals, bringing TSCA into harmony with the basic testing requirements recommended by the OECD and in force under the Sixth Amendment. The fate of this bill is not known (11).

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(6) 48 FR 21730.

(7) The dates and Federal Register references for the proposals and the amendments to the proposals may be found at 48 FR 21723 and 48 FR 41132.

(8) 48 FR 41132.

(9) 48 FR 21722-21764.

(10) 48 FR 41132-41140.

(11) (Current) Int'l Env. Rep. 7 : 72-73 (1984).

Another bill to amend TSCA is being considered and may be submitted during 1984. Support is apparently building for changes to TSCA, largely as a response to two recent reports. A National Academy of Sciences report indicated that 64% of chemicals reviewed under TSCA had little or no information with which to assess chemical health risks. An Office of Technology Assessment report indicated there was a lack of correlation between testing and potential chemical risks under the TSCA notification system (12).

Apparently consideration is being given to placing biotechnology under TSCA (13).

Purpose or Scope of the Legislation

The policy behind TSCA is clearly stated in the Act. Chemical substances and mixtures which present an "unreasonable risk of injury to health or environment" should be regulated, but not in a manner which would "impede unduly or create unnecessary economic barriers to technological innovation". Adequate data should be developed on the effect of chemical substances and mixtures, and such development of data should be the responsibility of the notifier (14).

Effective Date of Notification Requirement

TSCA came into effect on January 1, 1977. The interim PMN requirements came into effect on July 1, 1979. The final PMN requirements (with some exceptions) came into effect on October 26, 1983.

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(12) Tox. Mat. News 11 : 121-122 (1984).

(13) Tox. Mat. News 11 : 141 (1984).

(14) Subsection 2(b), TSCA.

Type of Notification

TSCA sets up a pre-manufacturing notification system in Section 5. The term "manufacture" includes importing (15). Section 5 also refers to "processing" (16). The system could be referred to as a pre-manufacturing, pre-processing and pre-importing system. However, the final rule does not require processors of new chemicals to submit a PMN.

Notification Time Period

Notice must be given to the EPA at least 90 days before a new chemical substance is manufactured, imported or processed (17). The notification period may be extended to 180 days or suspended if the notice is found to be incomplete.

Responsibility for Notification

Any person intending to manufacture or import a new chemical substance for a commercial purpose must notify the EPA. The final rule does not include manufacturers of a new chemical for export. It does, however, define "manufacturer" to include a person who contracts with a manufacturer to make a chemical substance exclusively for that person (18). This is sometimes known as "toll manufacturing".

When several persons are involved in importing a chemical substance, the "principal importer" must submit the notice (19). This phrase is defined (20) so as to clear up confusion as to who must submit a PMN in the case of importing (unlike the Sixth Amendment). There are also provisions in the final rule for joint submitters and agents. There is no longer a special PMN form for importers. Importers of new substances as part of articles are not subject to notification under the final rule (21).

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(15) Subsection 3(7), TSCA.

(16) Defined in subsection 3(10), TSCA.

(17) Subsection 5(a), TSCA.

(18) 720.22, 48 FR 21745.

(19) 720.22, 48 FR 21745.

(20) 720.3 (z), 48 FR 21744.

Although section 5 of TSCA refers to "processors" of new chemical substances, processors are not required to submit PMNs (22).

Notification Authority

Notices must be submitted to the Administrator of the Environmental Protection Agency.

Chemicals to be Notified

A "chemical substance" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical (23). It does not mean:

a) any mixture (24)
b) any pesticide
c) tobacco, etc.
d) nuclear material, etc.
e) firearms and ammunition
f) any food or food additive
g) any drug, cosmetic or device

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(21) 720.22, 48 FR 21745.

(22) 48 FR 21727. The preamble has a lengthy discussion on this point.

(23) Subsection 3(2), TSCA and 720.3(e), 48 FR 21743.

(24) The term "mixture" has an unintelligible definition, to be found in subsection 3(8), TSCA.

Chemical substances must be reported to EPA if they are "new", unless they are *exempt* new chemical substances. A *new* chemical substance is one which is *not* included in the TSCA Chemical Substance Inventory (25). Notifiers are responsible for determining if a chemical is "new" and this can be a problem because some substances are listed under generic names. The procedure for a notifier to determine if its chemical is a new one will be discussed, *infra* in the section concerning the TSCA inventory.

The new chemical substance must also be manufactured or imported "for commercial purposes" to require a PMN (26). The phrase is defined in the regulations for the final rule (27) as meaning the substance is:

a) distributed in commerce, including for test marketing

b) used by the manufacturer, including use for R&D purposes or as an intermediate

c) produced coincidentally during manufacture or use, including byproducts and impurities

It is noted that this definition is significant in its breadth; it certainly goes beyond the plain meaning of "commercial purpose". However, this definition is tempered by the following exemptions.

Exemptions

There are several types of exemptions which may apply to relieve the manufacturer or importer of a new chemical substance of the notification requirements.

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(25) Definition of "new chemical substance" is found in subsection 3(9) TSCA and 720.3(v), 48 FR 21744. The inventory is established and updated under subsection 8(b) TSCA.

(26) 720.22(a)(1), 48 FR 21745. It is not clear where the phrase "for commercial purposes" originates in TSCA itself; it is not in subsection 5(a).

(27) 720.3 (r), 48 FR 21744.

(a) Research exemption - if it will be manufactured or imported in small quantities solely for research and development (28). If the conditions for this exemption are met, there is no need for prior EPA approval. "Small quantity" means the amount "reasonably necessary" for R&D. This is a change from the interim condition of 1,000 pounds per year. There are a number of detailed conditions for this exemption.

(b) Test-marketing exemption - if it will be manufactured or imported solely for test-marketing purposes. This is not a total exemption as some information must be supplied to EPA (29). "Test-marketing" is a defined term (30). The most important benefit to this exemption is that EPA will act on the application within 45 days instead of 90 days. Restrictions may be imposed on the approval, however. A person must apply to EPA for this exemption. The regulations list the information required to obtain an exemption:

- (a) all existing data regarding health and environmental effects;
- (b) maximum amount to be manufactured or imported;
- (c) maximum number of persons who will receive the substance;
- (d) maximum number of persons who may be exposed to it;
- (e) estimated duration and routes of exposure; and
- (f) description of the test-marketing activity.

(c) Export exemption - if it will be manufactured or imported solely for export. This is a change from the interim rules. Some conditions apply (31). The phrase "manufacture solely for export" is defined (32) to include the following restrictions:

- (a) processing must occur only at sites controlled by the manufacturer;
- (b) distribution in commerce is limited to purposes of export;

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(28) 720.36, 48 FR 21746.

(29) 720.38, 48 FR 21746-7.

(30) 720.3(gg), 48 FR 21745.

(31) 720.30(e), 48 FR 21746.

(32) 720.3(s), 48 FR 21744.

(c) manufacturer itself may only use the substance in small quantities for R&D.

This provision may change. EPA intends to propose that manufacturers solely for export be required to submit notices to EPA under subsection 8(a) of TSCA (33).

(d) "No unreasonable risk" exemption - if it will be manufactured or imported under a rule made pursuant to subsection 5(h)(4) of TSCA (34). Subsection 5(h)(4) of TSCA allows the EPA to make a special exemption from all or a part of the PMN requirements if EPA determines that the substance "will not present an unreasonable risk of injury to health or the environment". What the EPA is doing under this provision is making a rule and it must do so in accordance with paragraphs (2) and (3) of subsection 6(c) of TSCA. This will mean a public hearing; "interested persons" will be allowed to make submissions.

(e) Other exemptions - the final rule provides that byproducts are exempt if they are not used for a commercial purpose (35); byproducts used for some specified commercial purposes may be exempt (36); impurities (37), nonisolated intermediates (38) and chemicals produced incidentally under a number of specified circumstances (39) are also exempt.

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(33) 48 FR 21726.

(34) 720.30(f), 48 FR 21746.

(35) 720.30(h)(2), 48 FR 21746. "Byproducts" is defined as a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. 720.3(d), 48 FR 21743.

(36) 720.30(g), 48 FR 21746.

(37) 720.30(h)(1), 48 FR 21746. "Impurity" is defined as a chemical substance which is unintentionally present with another chemical substance. 720.3(m), 48 FR 21743.

(38) 720.30(h)(8), 48 FR 21746. "Intermediate" is defined as any chemical substance that is ensumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions. 720.3(n), 48 FR 21743.

Proposed exemptions for polymers, low volume chemicals and site-limited intermediates are currently undergoing consideration.

Inventory

The TSCA Chemical Substance Inventory is administered and updated by EPA (40). The inventory currently lists about 50,000 commercial chemicals (41). A chemical substance is "new" if it is not on the list (42). Chemicals reported under the PMN requirements are added to the list after notice of commencement of manufacture or import has been given as not all chemicals that have been subject to a PMN enter commerce. This is significant in comparison to the European system in which subsequent manufacturers of new chemicals must submit a notice. EPA is authorized to list a chemical generically instead of individually (43).

Approximately 2000 chemicals are listed in the Inventory by a generic name to mask confidential chemical identity (44). It is the manufacturer's or importer's duty to determine if its chemical is "new". EPA has established procedures (45) to assist those who cannot tell if their substance is new due to generic listings. EPA will answer such person's inquiry if they show a bona fide intent to manufacture or import the substance (46). EPA will respond to these inquiries within 30 days. EPA will inform the original notifier that an inquiry has been made (47).

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(39) 720.30(h)(3)(4)(5)(6)(7), 48 FR 21746. These are extensive; they include chemical substances produced incidentally during processing, storage, disposal, etc. of other chemicals.

(40) Subsection 8(b), TSCA.

(41) Hinds (1983), p. 21.

(42) Subsection 3(9), TSCA.

(43) Subsection 8(b)(2), TSCA.

(44) Klein (1983), p. 33.

(45) 720.25(b), 45 FR 21745.

(46) The only difference between the final rule and the interim measures is that, currently, a sample of the substance need not be supplied to EPA with the inquiry, 48 FR 21728.

(47) 48 FR 21728.

There are two non-confidential inventories; a published version and a master inventory. The latter contains the latest substances added to the inventory and not yet published. EPA will check the master inventory without requesting proof of a bona fide intent (48).

Content of Notification

The ten-page final form for PMNs was published in May of 1983 (49). The amount of mandatory information required in the final form has decreased from the interim measures. EPA's current policy is that detailed information is not necessary on the initial notice form. It is thought that Form 7710-25 contains sufficient information to identify substances of concern, that will require further information (50).

EPA is counting on voluntary cooperation on the part of notifiers if further information is required. A lack of cooperation will invite regulation of the substance pending submission of the information (51).

There is no longer a distinction between a manufacture PMN and an import PMN. Persons may obtain pre-notice approval to submit a "consolidated" notice if two or more structurally related substances are to be notified (52).

The final form is in three parts:

(a) Part I - General Information

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(48) Hinds (1983), p. 22.

(49) 48 FR 21755-21764.

(50) 48 FR 21729; see also Klein (1983) generally. The requirements are limited to those clearly specified in subsections 8(a)(2)(A) through (G) except (E) and information which reasonably falls within the intent of subsection 5(d)(1), TSCA.

(51) 48 FR 21729; authority for this approach is found in subsection 5(e), TSCA.

(52) 48 FR 21734-35.

(b) Part II - Human Exposure and Environmental Release
(c) Part III - List of Attachments

General information requested in Part I of the final form (53) is as follows:

(a) identity of the new substance (54);
(b) anticipated impurities;
(c) byproducts resulting from manufacture, processing, use or disposal (at sites controlled by notifier);
(d) estimated maximum amount to be produced (55);
(e) use information and estimated production volumes for each use.

Part II of the form requests information to be supplied regarding human exposure and environmental release. The notifier is requested to provide a process description for the manufacture, processing or use at every site controlled by the notifier:

(a) location of site;
(b) nature of the process;
(c) amount and duration of production, processing or use;
(d) diagrams of operation steps and chemical conversions;
(e) identify points of release to the environment.

Occupational exposure information includes:

(a) job descriptions for exposed workers;
(b) physical form(s) of substance at time of exposure;
(c) maximum number of workers in each activity.

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(53) 720.40, 48 FR 21747.

(54) There is a separate portion of the form for the generic chemical name developed with EPA during prenotice communication.

(55) During the first 12 months and any twelve month period in the first three years of production.

Environmental release and disposal information includes:

(a) estimated amount of substance released (in kg/day or kg/batch);
(b) media of release;
(c) description of release control technology;
(d) identity of destination(s) of releases to water.

A second portion of Part II requests information regarding industrial sites controlled by others. Items similar to the above are requested although in less detail.

Part III of the final form is the list of attachments, which would include:

(a) continuation sheets;
(b) test data;
(c) option data such as risk assessment, analysis of ultimate environmental fate, etc.;
(d) copies of hazard warning statement, labels, etc.

Notifiers must submit with their PMN all "test data" in their possession or control which are related to the substance's effect on health or the environment (56). This applies to the pure substance, technical grade or formulations. The definitions of "test data" and "possession or control" are very broad (57). A full report must be submitted on the following types of test data (58):

(a) health effects data;
(b) ecological effects data;
(c) physical and chemical properties data;
(d) environmental fate characteristics;
(e) monitoring data related to human exposure or environmental release.

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(56) 720.50 48 FR 21748; subsection 5(d)(1)(B), TSCA.

(57) For example, if a notifier has purchased access to a data base, the notifier has "possession or control" of that information.

(58) 720.50(a)(2), 48 FR 21748.

In addition to test data, the notifier is required to submit "other data" concerning the health and environmental effects of the substance that are known to or reasonably ascertainable by the notifier. A "description" of "other data" must be attached to the form (59).

The EPA Instructions Manual for the final form describes "optional information" which would be helpful in EPA's review such as (60):

(a) relative risk;
(b) process chemistry;
(c) efficacy;
(d) additional exposure and environmental release information;
(e) industrial hygiene;
(f) engineering safeguards;
(g) use restrictions;
(h) economic and other benefits.

Other than confidential data, the following are data exempt from submission requirements (61):

(a) data previously submitted to EPA;
(b) data related solely to product efficacy;
(c) data on human exposure or environmental release outside the U.S.

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(59) 720.50(b), 48 FR 21748-9.

(60) Hinds (1983), p. 31.

(61) 720.50(d) 48 FR 21749.

Submission of New Information

During the notice review period, if the notifier possesses, controls, or knows of new information that is significant, that information must be submitted to EPA, even if it requires a telephone call during the last five days of the review period (62).

Testing Requirement

EPA has issued testing guidelines as to what test data should be generated (63). It is recommended that notifiers use the OECD Minimum Pre-market Data (MPD) scheme as a starting point, but a submission meeting the requirements of TSCA without the MPD would be complete (64). The U.S. system does not require specific tests to be done for a PMN submission. The catch is, of course, that if EPA is not satisfied with the information supplied in a PMN, and if the substance may present an unreasonable risk, the EPA may issue an order barring or restricting manufacture of the new substance until further information is supplied (a subsection of 5(e) order) or it may find the substance poses an unreasonable risk and issue an order barring or restricting the manufacture or use of the substance outright (a subsection 5(f) order). The lack of information in itself is not sufficient reason for such actions, see infra.

Mutual Acceptance of Data

The U.S. system is independant of those of other nations. There is no provision in the regulations for the acceptance by EPA of data submitted to another jurisdiction in satisfaction of the PMN requirements. However, the U.S. is committed under the OECD chemical control to accept data from other nations, although this does not mean that it will accept hazard assessments.

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(62) 720.40(f) 48 FR 21747.

(63) 46 FR 8986 (January 27, 1981).

(64) 48 FR 21740.

Further Testing Requirements/Follow-Up Measures

As indicated above, EPA has the authority under TSCA to issue an order barring or restricting the manufacture of a substance until further information is supplied. This can only be done during the review period, so in a sense it is a limited form of a "further testing" requirement (if it can even be called that). For such a subsection 5(e) order EPA must find that insufficient information was supplied and the substance may present an unreasonable risk to health or the environment or the substance will be produced in substantial quantities and there may be significant human exposure or release to the environment. EPA has authority to extend the review period (65). If EPA has not taken action during the review period, the notifier is free to go ahead with manufacturing or importing the substance as soon as the notice review period expires. The notifier must then inform EPA when manufacture or import begins and the substance is added to the Inventory (66).

Special Orders

There are two types of "follow-up rules" other than the regulatory responses allowed by subsections 5(e) and (f) of TSCA:

(a) Further reporting rules - Subsection 8(a) rules - EPA will promulgate follow-up reporting rules on certain new chemical substances. Such rules will allow EPA to obtain information on selected new chemical substances after they have entered commercial production. EPA has proposed such subsection 8(a) rules for chemical substances in the Federal Register and will continue to do so. These rules will be used primarily to monitor changes in exposures to chemicals of concern (67).

(b) Significant new use rules (SNURs) - Subsection 5(a)(2) rules - EPA is authorized to issue SNURs so as to reassess certain new chemicals before they are produced for new uses that may significantly increase their risk to human health or the environment. A

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(65) Subsection 5(c), TSCA.

(66) The "notice of commencement" must contain specified information, 48 FR 21725.

(67) See 48 FR 21740.

SNUR requires persons to notify EPA 90 days before they manufacture, import, or process the substances subject to the rules for a significant new use. The same reporting requirements, review procedures, and authorities that apply to notices for new substances apply to SNUR notices. If EPA does not regulate the chemical after receiving a SNUR notice it must state its reasons in the Federal Register (68).

Protection of Confidential Data

There is a strong emphasis in the U.S. system on the protection of confidential information during the PMN process. The Act allows a notifier to claim confidentiality for any information submitted to EPA (69) but this is not absolute (70). The Act provides that in certain circumstances the public interest outweighs the private business interest. Balancing these interests has resulted in considerable complexity in the administration of the Act. A general outline of policy considerations has been published (71).

Some of the confidentiality provisions are as follows:

(a) Assertion of claim - to claim confidentiality for information in a PMN, a notifier must make the claim when submitting the notice; this is done by checking the appropriate box on the final form (72). A notifier claiming confidentiality must submit a PMN with all information present and a "sanitized copy" with the confidential information deleted (73).

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(68) Ibid.

(69) Section 14, TSCA.

(70) Subsections 5(d)(1) and (2), TSCA.

(71) 48 FR 21737-8.

(72) 720.80(b)(1)(ii), 48 FR 21751.

(73) 720.80(b)(2), 48 FR 21751. Through September, 1982, confidentiality claims were submitted on approximately 94% of all PMNs. In 3% of PMNs a confidentiality claim was made for the entire PMN, Klein (1983), p. 33.

(b) Substantiation of claim - EPA no longer requires "up-front" substantiation of a claim for confidentiality in the PMN. However, a confidentiality claim for chemical identity must be substantiated when the notice of commencement of manufacture is submitted. This is a substantial change from the interim PMN procedures (74).

(c) Specific chemical identity - detailed provisions apply for a confidentiality claim for specific chemical identity. A notifier must propose an acceptable generic name for the substance; it must be only as generic as necessary (75).

(d) Prior to commencement of manufacture or import - separate confidentiality claims for the periods prior to, and after, commencement of manufacture or import must be made (76). The generic name provision applies to the period before commencement of manufacture or import. For this claim for confidentiality to be allowed, disclosure of the fact that the notifier intends to manufacture or import the substance must in itself reveal confidential business information.

(e) After commencement of manufacture or import - to maintain the confidentiality claim after commencement of manufacture or import, the notifier must assert another confidentiality claim and substantiate the claim in the Notice of Commencement (77). After inclusion of the generic name in the Inventory, the notifier may be required to provide certain chemical identity information (eg: elemental analysis, mass spectrum) to EPA on request so that a bona fide request from another person for further information (to see if their substance is "new") may be answered by EPA (78).

(f) Confidential uses - to prevent disclosure of a chemical substance's uses, a confidentiality claim must include a non-confidential generic description of uses (79).

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(74) 48 FR 21738-39.

(75) 720.85(a)(2)(ii), 48 FR 21751; see discussion supra under section on Inventory.

(76) 720.85(a)(1),(b)(1), 48 FR 21751.

(77) 720.85(b)(1), 48 FR 21751.

(78) 720.85(b)(3)(iii),(5)(iii), 48 FR 21752.

(79) 720.87(b), 48 FR 21753.

(g) Data in health and safety studies - the final rule contains specific provisions limiting claims of confidentiality for information contained in a health and safety study (80).

Disclosure of Data and Proprietary Rights

Once a substance is listed in the Inventory, it is no longer new. A subsequent manufacturer or importer of that substance does not have to submit a PMN. Therefore, there is no need for other persons to negotiate for the use of data previously submitted by an "original notifier" as in the European system (81).

Public Participation

EPA has a responsibility to provide meaningful information to the public concerning new chemicals. A section 5 PMN must be made available for "examination by interested persons" subject to the section 14 confidentiality provisions (82). EPA has a responsibility to publish a notice in the Federal Register upon receipt of a PMN. The notice must identify the substance, list the intended uses and describe test data - also subject to the confidentiality provisions (83).

There are further responsibilities (84):

(a) Petitions - the Act contains a variety of provisions under which citizens can petition EPA to take particular actions on section 5 notices.

(b) Freedom of Information Act (FOIA) - under FOIA, persons may request disclosure of any information submitted in a PMN. EPA must then review information subject to a claim for confidentiality. If EPA determines the information is confidential, the FOIA requester may bring an action in the Federal Court to review EPA's decision.

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(80) 720.90, 48 FR 21753.

(81) See discussion supra under section on Inventory.

(82) Subsection 5(d)(1), TSCA.

(83) Subsection 5(d)(2), TSCA.

(84) See generally 48 FR 21737-38.

(c) Public record - with respect to EPA's rule-making process, EPA must maintain a public record documenting the information on which the rule-making process is based. Confidential business information is not included in the public record (85).

Enforcement and Penalties

The Act provides for various offences (86) such as:

(a) failure to comply with any requirement, rule or order pursuant to sections 5 and 6 of the Act;

(b) use of a substance for commercial purposes which the person knew was manufactured, etc., in violation of the Act;

(c) failure to maintain records as required by the Act;

(d) failure to permit access to records or entry or inspection;

(e) submission of materially misleading or false information.

Violators may be subject to criminal and civil liability. Fines of up to $25,000 for each violation may be imposed. Imprisonment may be up to one year. EPA may obtain injunctions to restrain violations and may seize substances manufactured, etc. in violation of the Act (87). EPA is also authorized to conduct inspections (88).

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(85) Subsection 19(a)(13) TSCA; see also 48 FR 21742.

(86) Section 15, TSCA; see also 48 FR 21737.

(87) Sections 5,16,17, TSCA.

(88) Section 11, TSCA.

3.14 YUGOSLAVIA

The Socialist Federal Republic of Yugoslavia is a communist country, the only one involved in the OECD. Yugoslavia is not a member of the OECD. It participates in many of the organization's activities and so it has a "special status". As a communist country, the basis of the social and political system is social ownership of the means of production and social self-government by the citizenry in the processes of production and distribution of the national income.

It is beyond the scope of this review to delve into all of the differences which flow from the fact that Yugoslavia is a communist country insofar as chemical control legislation is concerned. It is difficult to assess a country's legal response to a situation when that legal response is in the context of a "closed society" - there is little opportunity in communist societies for dissenters to point out the difference between what the printed law states and what actually occurs.

From first principles, the political theory of chemical control in a communist society would differ radically from that in a capitalist society. In the latter the owners of capital are free to do what they will without anyone knowing about it unless the government decides to step into the commercial arena and by law requires compliance with specified demands. Aside from state or Crown corporations, the owners of capital are distinct from government entities in capitalist societies. Governments must legislate the mechanisms by which they can become informed of the activities of business - they have no inherent right to know otherwise. In a communist country such as Yugoslavia there is no such distinction between the owners of the means of production and the government. Insofar as chemical control legislation is concerned, the "right to know" might be meaningless in such a centrally planned economy - it would be a question of the right hand demanding to know what the left hand is doing (1).

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(1) As an aside, it might be said that the foregoing discussion regarding the distinction between the owners of capital and the government in Western societies is predicated on the concept of the "right to property". The deletion of the express right to property in Canada's new Constitution occurred with little subsequent discussion as to what effect this will have on the fundamental nature of Canada's political and legal systems.

Yugoslavia is a federal state. The Federal Assembly nominates the highest executive bodies of the country. The federation is comprised of a number of republics (2). A lower level of government organization is the province.

The chemical industry in Yugoslavia is relatively well developed (3). Chemicals constituted 12% of Yugoslavia's major exports in 1981 (4).

Overview

Yugoslavia has enacted the Poisons Trade Act (5) and has issued Regulations On More Specific Criteria for Classifying Poisons and on Methods for Determining Degree of their Toxicity (6) pursuant to that Act.

The Yugoslavian legislation is similar to that of Switzerland and New Zealand in that it is oriented toward regulating the trade in toxic substances rather than notification of new industrial chemicals. In Yugoslavia, "poisons" may not be marketed or used unless a toxicological evaluation of the poison indicates that its use for its prescribed purpose is not harmful to humans or the "human environment" (7). Chemicals are not notified to the competent authority but rather an application is made for the classification of poisons. Marketing conditions are then based on the classification.

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(2) Encycl. Brit. 19 : 1104-1105 (1974).

(3) Popvic (1981).

(4) Encycl. Brit. (1983).

(5) Poisons Trade Act, Official Gazette of the Socialist Federal Republic of Yugoslavia, No. 43, July, 1982.

(6) Regulations On More Specific Criteria for Classifying Poisons and on Methods for Determining Degree of their Toxicity, issued November 25, 1982 by the Federal Committee for Labour, Health and Social Welfare. A reference in the official Gazette is not readily available.

(7) Article 3 - Act.

Status of Implementation

The Yugoslavia legislation mentioned above is currently in place.

Purpose or Scope of the Legislation

The purpose of the Act is expressly stated to be the protection of human lives and health and the human environment from the harmful effects of poisons (8).

Effective Date of Notification Requirement

The Act came into force in July of 1982 but was not applied until 60 days later, sometime in September of 1982 (9). However, the provisions of the Act requiring toxicological evaluations of poisons does not come into effect until September of 1984 (10) except in the case of those using poisons for primary production in industry, in which case the evaluation requirement does not come into effect until September, 1985 (11).

But these extensions refer to "organizations of associated labour" (discussed infra) and not foreign manufacturers. The implication is that the evaluation requirement is currently in force for those importing into Yugoslavia.

Type of Notification

A poison must be classified before marketing or use. The application for classification may be referred to as notification. Hence, the Yugoslavian system may be called a pre-marketing and pre-use notification system. The Act also refers to application being made by those who produce or import the poison so it may also be called a pre-manufacturing and pre-importing scheme (12).

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(8) Article 1 - Act.

(9) Articles 53 and 54; the exact date cannot be known unless the date in July on which the Act was published in the Official Gazette is known.

(10) Article 49 - Act.

(11) Article 50 - Act.

There is a separate provision in the Act regarding notification. Within 8 days of marketing a poison an "organization of associated labour" must notify all the republican and provincial authorities in charge of health that it has done so. The notification must be accompanied by a declaration and instructions for use. Further, the organization of associated labour using a poison for primary production in industry must notify that fact to the republican and provincial governments (13). The declaration is likely that referred to as accompanying the packaging of poisons (14). This limited form of notification might be called post-marketing and post-manfacturing notification. It is not clear whether this type of notification is a continuing notification or if it is done once per poison or once per entity marketing or manufacturing the poison.

Notification Time Period

A notification time period similar to the 45 day period in the Sixth Amendment is not provided for the Yugoslavian legislation.

Responsibility for Notification

Individuals are absolutely prohibited from trading in poisons. Only "organizations of associated labour" are permitted to trade in poisons (15). "Organizations of associated labour" is an undefined phrase. Knowing what little we do of the structure of communist societies, it may be assumed that they are the industrial units which are collectively owned by the Yugoslavian people. The notification is to be submitted by the organization of associated labour involved, or, in the case of a foreign manufacturer by its authorized agent in Yugoslavia (16).

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(12) Article 15 - Act.

(13) Article 37 - Act.

(14) Article 26 - Act. This information contains the name of the poison, content of active substances, date of manufacture, period of use, identity of the manufacturer and the method of storing.

(15) Article 7 - Act.

Notification Authority

The Act provides that notification must be submitted to the "federal administrative authority in charge of health affairs" (17). The Regulations issued pursuant to the Act were made by the Federal Committee for Labour, Health and Social Welfare, leaving the impression that the latter is the notification authority.

The Act states that the decision on the classification of poisons is to be made by the official in charge of the federal administrative organ in charge of health affairs on the basis of the opinion of the Commission for Poisons. The latter is a federal commission composed of experts from a variety of fields. Both the federal authorities and the republican and provincial authorities have some input as to the membership of the Commission (18).

Who does the toxicological evaluation? The federal authority in charge of health, on the proposal of the Commission, specifies which organizations of associated labour are to perform toxicological evaluations. Authorization to perform the evaluations cannot be given to an organization of associated labour which manufactures or markets poisons (19). The organization of associated labour forms an expert commission to review the "proposal" received from a manufacturer and arranges for analytical tests to be done at the manufacturer's expense (20). There is no indication that the "proposal" contains any specific information.

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(16) Article 15 - Act.

(17) Ibid.

(18) Article 16 - Act.

(19) Article 35 - Act.

(20) Article 36 - Act.

Chemicals to be Notified

The Yugoslavian legislation refers to "poisons". This term is defined to mean substances of synthetic, biological or natural origin and preparations produced from such substances, which can, after entering the organism or in contact with it, endanger the life or health of humans or have an adverse effect on the human environment (21).

It is clear that the legislation is not aimed at chemical substances generally. By requiring notification of "poisons", a potential notifier must first determine if the substance in question is a poison. The legislation is also not aimed at "new" chemicals but then, a poison is "new" up until it has been evaluated, as all poisons must be evaluated; there is no distinction between "existing" and "new" chemicals. Once a poison has been evaluated and classified it is placed on a list according to its classification.

The only further notification would be the limited submission of information to republican and provincial authorities noted supra as post-marketing/post-manufacturing notification.

The Yugoslavian legislation does not apply to drugs which contain poisons or to poisons used for laboratory or scientific purposes (22).

Exemptions

None are noted in the Act.

Inventory

Other than lists of classified poisons (23), there is no inventory required by the Yugoslavian system.

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(21) Article 2 - Act.

(22) Article 11 - Act.

(23) Article 42 - Act. The list of poisons classified into groups is to be published in the Official Gazette.

Content of Notification

The application for classification must contain a toxicological evaluation and, if the substance is imported, proof that the substance is not prohibited in the manufacturer's country (24).

However the toxicological evaluation as discussed above, is not done by either the manufacturer, etc. or the competent authority. It is done by an authorized organization of associated labour - which cannot itself deal in poisons. The manufacturer makes a "proposal" to the authorized entity, but there is no indication of what, if anything, the proposal contains, other than a request for an evaluation.

Regulations have been issued which set out what the authorized organization must consider when doing an evaluation (25). The criteria given cover an enormous range of data.

Testing Requirements

As mentioned, the criteria which the authorized organization must consider when performing an evaluation is extensive (26):

(a) physical and chemical properties - these are further set out in the Regulations to include most of the physico-chemical data contained in Annex VII of the Sixth Amendment (27);

(b) toxicological properties - these properties are further broken down to include eleven properties which ranges from acute oral, dermal and inhalation toxicity to teratogenicity. Nothing seems to be left out (28);

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(24) Article 15 - Act. Poisons prohibited in a foreign manufacturer's country are also prohibited in Yugoslavia.

(25) See footnote 5.

(26) Article 2 - Regulations.

(27) Article 3 - Regulations.

(c) ecotoxicological properties - these properties include acute toxicity in several species as well as biodegradation and bioaccumulation (29);

(d) microbiological properties - six microbiological properties are listed (30);

(e) suitability of application in public hygiene;

(f) protection and first-aid measures;

(g) procedure for destruction and/or elimination of the poison;

(h) volume of domestic production and consumption - this includes imports.

The Regulations set out the methods to be used for determining the toxicological and ecotoxicological properties of the poison (31). The evaluation should include data which is similar to the identity of substance data in Annex VII of the Sixth Amendment (32).

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(28) Article 4 - Regulations.

(29) Article 5 - Regulations.

(30) Article 6 - Regulations.

(31) Articles 7 and 9 - Regulations.

(32) Article 14 - Regulations.

Mutual Acceptance of Data

As mentioned, if a substance is prohibited in the importer's own country it is prohibited to bring it into the country. This could be thought of as a reverse type of mutual acceptance of data.

Flexibility in Notification Requirement

There is no indication whether there is any flexibility in the information to be submitted to the competent authority for the purpose of poison classification. Nor is there any indication of flexibility in the criteria which the authorized organization use to evaluate poisons.

Further Testing/Follow-up Measures

The tests set out in the Regulations are not organized in a step sequence. All the criteria are to be considered.

As mentioned above, there is a further requirement to notify the republican and provincial authorities within 8 days of the release of a poison in the market.

Upon classification, other provisions of the Act come into play regarding labelling, packaging and use. There is no provision for reclassification or for further data submission upon change in circumstances.

Special Orders

The federal authorities appear to operate the classification system and matters relating to transborder trade, but many of the other provisions of the Act are under the jurisdiction of the republics and provinces (33).

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(33) Article 40 - Act.

All authorities have, in their areas of jurisdiction, the power to prohibit trade in poisons if the provisions of the Act are not carried out. There is a general power to order a poison withdrawn from the market and destroyed if it appears to be harmful to human health or the environment (34).

Protection of Confidential Data

There are no express provisions for the protection of confidential data.

Disclosure of Data and Proprietary Rights

The federal government is authorized to publish the list of poisons classified into groups, but there is no indication that the extensive information developed during the evaluation process is released. However, that information is in the hands of neither the producer/importer or the government itself - it is generated by an authorized organization. The Yugoslavian legislation does not indicate what happens to this information. The status of "proprietary rights" to information in a communist country is not clear. A foreign manufacturer does not provide information to the authorized organization which does the evaluation so there is no apparent risk to proprietary rights to data which the foreign manufacturer may have generated on its own.

Public Participation

There are no provisions for public participation in the Yugoslavian legislation. What does "public participation" mean in a communist country?

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(34) Article 41 - Act.

Enforcement and Penalties

Those dealing in the unauthorized production, processing or marketing of poisons shall be sentenced to imprisonment for a term ranging from 6 months to five years if the offence is a criminal offence (35). "Economic violations" such as trading or using a harmful poison or marketing or using a poison before it is classified are subject to a fine of 100,000 to 1,000,000 dinars (36). A separate fine of 5,000 to 30,000 dinars shall be imposed on the "responsible person" in the organization of associated labour or other legal persons for such economic violations (37). Other penalties apply to violations with respect to advertising, handling and occupational health and safety (38).

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(35) Article 43 - Act.

(36) Article 44 - Act.

(37) Ibid.

(38) Article 45 - Act.

COMPARISON OF THE SIXTH AMENDMENT AND TSCA

Why should the EEC Sixth Amendment and TSCA be compared? Certainly not because either or both are models of perfection which should be emulated for that reason alone. Perfection is not an attribute of legal systems. It would be fair comment to allege that the Sixth Amendment is too simple and inflexible and TSCA is too complex and flexible. It is important to understand the similarities and differences of these two systems because they govern two powerful economic units with large chemical industries. Many practical difficulties can be foreseen if a country such as Canada, which has extensive trade with both entities, should establish a new chemical notification system radically different from either or both the Sixth Amendment and TSCA.

In one sense, it is inappropriate to attempt to compare the Sixth Amendment and TSCA. This is because they are two very different kinds of instruments. As discussed supra, the Sixth Amendment is a Directive of a supra-national entity requiring Member States to enact or amend their national laws to conform to the rules set out in the Directive. National legislation must conform in substance to the Directive and cannot contradict it. However, details of implementation can differ widely between Member States. Thus, the Directive, because it is not legislation but directs legislation, is phrased in general terms.

TSCA on the other hand, is a specific piece of national legislation. As with most Acts or Laws, it is "enabling legislation". That is, the legislation contains specific rules but it also enables the government authorities to issue subsidiary rules in the form of regulations. It is relatively difficult to amend an Act but the details of implementation set out in the regulations can vary greatly over time. In a sense, the American system is in a constant state of evolution.

Aside from this difference in nature between the Sixth Amendment and TSCA, they both represent a system of notification for new industrial chemicals. As such they must both have some basic elements that can be compared easily, eg. who must notify the authorities?; what types of chemicals must be notified?, etc. Where there is an emphasis or a specific concern, the details of the two systems differ widely and comparison is difficult. For example, two major characteristics of the Sixth Amendment are: 1) specific test data results are required; and 2) additional test data results are required when quantities of chemicals marketed reach certain levels. A major emphasis in TSCA (and not emphasized in the Sixth Amendment) is the protection of confidential data. Consequently, in the Sixth Amendment details of required test data are extensive and in TSCA details of confidential data are extensive.

Another important difference between the Sixth Amendment and TSCA which is not well reflected in the table infra, is the difference in legal, social and cultural context. As noted in the Introduction to this report, laws are not readily transposed between jurisdictions. Despite the development of the "global village", a European is very different from an American. The French laws on notification are printed on half a dozen pages, the American laws on the same subject are enormously long. Why?

A European and an American have radically different expectations of their laws and their enforcing bureaucracies. In general, European laws are drafted by the bureaucrats who will enforce them whereas the U.S. Congress is more independent in the development of legislation. Legislation in Europe results from behind the scenes consensual negotiation but in the U.S. it is the product of open adversarial debate.

Europeans have democracies which emerged from autocracies and there is a lingering deference to government authority, a respect for bureaucracy and an acceptance that bureaucrats will have much informal discretion and power. The American democracy emerged from an anarchaic frontier society and there is a lingering defiance of authority, a distain for bureaucracy and an acceptance that if one doesn't like a law or a bureaucrat's actions one proceeds to the courthouse.

In Europe, bureaucrats are normally with the organization for life (memories are long) whereas in the U.S. there is a continuous flow of personnel between government service and private business (memories are short). A European businessman will submit to government authority for the sake of the longterm relationship but in the U.S. a businessman will litigate every loosely worded provision in the law he can find.

Generalities, perhaps, but very real. Just as it is frequently more important how a person holds his beliefs than what he believes, so it is frequently more important what the context of a legal system is than what the law says.

The question remains: why compare the Sixth Amendment and TSCA? If it is kept in mind that they are by nature two very different kinds of instruments and that their contexts are also very different, their examination and comparison can be revealing. This is especially so if the examination is done from a Canadian perspective. Of all the nations in the world, Canada is the nation which is at the crossroads of European and American influences. So many Canadian attributes are midway between European and American characteristics.

If any nation can forge a new and different system, attuned to its own needs, that is compatible with both the European and American systems, it is Canada. A third element, that of consistency with the international harmonization efforts of the OECD chemical control program, must also enter the analysis.

	EEC SIXTH AMENDMENT	U.S. TSCA
Type of control mechanism.	A Directive of a supra-national sovereign entity addressed to Member States.	An extensive Act and regulations of an individual nation.
How is the control mechanism implemented?	Member States obliged to change national laws to conform with the substance of the Directive with considerable choice of form and method.	The enabling Act is implemented by regulations which are in an on-going process of amendment.
When did it come into effect?	Member States must have implemented the Directive by September 18, 1981. Not all did.	Act was passed in 1976. Interim system began July 1, 1979. Final system began October 26, 1983 (with several provisions stayed).
Purpose or scope.	To protect man and the environment while facilitating trade in common market by harmonizing national laws.	To prevent unreasonable risk of injury to health or environment without impeding technological innovation.
Type of notification.	Pre-marketing and pre-importing notification.	Pre-manufacturing and pre-importing notification.

EEC SIXTH AMENDMENT	U.S. TSCA
Is the notification requirement "open-ended" and continuous?	
Yes. Subsequent marketing and importing of a substance must be notified because notification does not cause entry into inventory.	No. Once importation or manufacture of the reported substance has commenced the chemical is placed on the inventory and subsequent notification is not required.
Notification time period.	
Notification must be given at least 45 days before marketing or importing.	Notification must be given at least 90 days before manufacturing or importing.
Responsibility for notification.	
"Manufacturer" or "importer" who will place the substance on the market. Neither term is defined.	Any person intending to manufacture or import for commercial purposes. "Manufacturer" and "importer" precisely defined.
Notification authority.	
Member States obliged to appoint a competent authority or authorities to receive notifications.	Administrator of the Environmental Protection Agency.
Does the notification authority "licence" a substance?	
No. The competent authority does not "licence" or "approve" of a substance; it only "disapproves". The notifier is free to market or	No. The competent authority does not "licence" or "approve" of a substance; it only "disapproves". The notifier is free to manufacture

	EEC SIXTH AMENDMENT	U.S. TSCA
	import the substance after the notification time period unless the competent competent authority acts.	or import the substance after the notification time period unless the the competent authority acts.
What chemicals, etc. are excluded?	Medicines, narcotics, radioactive substances, carriage of dangerous substances, foodstuffs, feedingstuffs, waste material, substances in transit under customs control, pesticides and other substances if similarly regulated.	Mixtures, pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, cosmetics, devices.
What chemicals, etc. are covered?	Substances not marketed before September 18, 1981 and eventually substances not in EINECS inventory.	Substances not in the Chemical Substance Inventory.
Are preparations or products covered?	Preparations are not notified but substances in preparations may be. No reference to products.	Mixtures not covered. No mention of preparations or products - neither in definition of "substance".
Exemptions.	Yes, a few general.	Yes, many specific.
Exemption for polymers.	Yes, except if contains 2% or more of a notifiable monomer.	No, but exemption is being considered.

	EEC SIXTH AMENDMENT	U.S. TSCA
Exemption for test-marketing.	No.	Yes, but the test-marketing exemption must be applied for along with c data package. EPA approval required.
Exemption for research, development and testing.	Yes, if less than one tonne and solely for laboratory. Some data submitted if "very toxic" or "toxic". If greater than one tonne, limited data are required.	Yes, the final PMN rule has no quantity stipulation.
Exemption if chemical is exported.	No.	Yes, but some restrictions are being considered.
Exemption if under other rule?	No.	Yes, if under statutory rule that substance offers "no unreasonable risk". However, rule-making is required for each case.
Exemption for byproducts.	No.	Yes, if not used for a commercial purpose (although use for some specified commercial purposes also exempt).

	EEC SIXTH AMENDMENT	U.S. TSCA
Exemption for impurities.	No.	Yes.
Exemption for intermediates.	No.	Yes, if non-isolated.
Exemption if small quantity is marketed or manufactured.	Yes, if less than one tonne per year per person. Some information must be notified.	No, although an exemption for low volume chemicals has been proposed.
Exemption if notified a long time ago.	Yes, if the substance has been previously notified at least 10 years ago. Some information must be notified.	No, does not apply.
Is there an inventory?	Yes.	Yes.
What is the nature of the inventory?	Substances which Commission knew had been marketed before September 18, 1981 entered in ECOIN inventory. Final EINECS inventory to be published in 1985 includes ECOIN inventory and substances declared to be pre-September 18, 1981 by their manufacturers or importers.	After notice of commencement of manufacture or import of a new substance is received, the chemical is added to the inventory.

	EEC SIXTH AMENDMENT	U.S. TSCA
How is the inventory used?	Six months after EINECS is published in 1985, a substance will be "new" and require notification if it is not on the list. Once "new" always "new" (for 10 years).	Any substance not on inventory is "new" and requires notification.
What is the form or vehicle for notification?	A technical dossier, a declaration and proposals. No form is provided for. Details set by Member States.	A 10 page final form for notification published in 1983.
What is included in the notification?	Results from specified Annex VII tests, declaration of unfavourable effects, proposed classification and labelling and recommended precautions.	The form requests or "invites" information to be submitted, covering topics similar to Annex VII.
Are the contents of the notification mandatory?	Yes.	Some basic data is mandatory. The rest is to be provided to the extent it is known or reasonably known. Therefore specific information can only be defined on case-by-case basis.
Is information submitted during the notice review period?	No.	Yes, even if it means a telephone call.

	EEC SIXTH AMENDMENT	U.S. TSCA
Is there specific information not required in the notification?	No.	Yes. Data previously notified, data related solely to product efficiency and data on human exposure or environmental release outside the U.S.
Is optional information listed for inclusion in the notification?	All information necessary for evaluation is to be submitted and it is to contain at least Annex VII data. But no optional data actually listed.	Yes. A list with 8 categories of optional data is noted.
Are specific test data required in the notification?	Yes. Annex VII test results. Data must be generated by notifier.	No. Generation of test data is not required.
Are specific test data suggested?	Only for Annex VIII tests where certain quantities of substance marketed or imported are reached.	Yes. Categories of data are listed. OECD MPD is suggested.
Flexibility in notification requirements - ommission/substitution of data.	The "base set" of data in Annex VII can be modified if "it is not technically possible", etc. to give the information. There is also flexibility in the Annex VIII test requirements. Reasons must be given.	EPA has issued test guidelines. However, testing or MPD is not required. All information "known or reasonably ascertainable" must be supplied. Allows flexibility.

EEC SIXTH AMENDMENT	U.S. TSCA
Is further testing required after the first notification?	
Yes, if quantities marketed or imported reach certain levels then Annex VIII tests required. If necessary, further information and/or verification tests can be requested, including Annex VIII data before levels are reached.	Only if EPA issues an order barring manufacture until further information supplied, but this power is contingent on unreasonable risk being evident.
Is further data required after the first notification?	
Yes, notifiers must keep competent authority appraised of changes in quantities, new knowledge of effects, new uses, and any change in properties caused by modification of composition.	Only during review period. After notification, notifier need only tell EPA when manufacture or import begins. No on-going provision of data unless EPA issues a rule.
Special orders.	
Member State may provisionally prohibit sale if substance constitutes a hazard.	EPA can ban outright, ban pending further data, issue a rule requiring data on selected new chemical after manufacture and can issue a SNUR.
Is there provision for the protection of confidential data?	
Yes. A blanket provision exists for secrecy as well as provision for notifier to indicate specific confidential data.	Yes, but only if notifier requests.

EEC SIXTH AMENDMENT	U.S. TSCA
Does the notifier have to assert a claim for confidentiality?	
Notifier can also specify which data are confidential.	Yes. Notifier must check appropriate box on notification form.
Must a claim for confidentiality be substantiated?	
Yes.	Substantiation is no longer required except for chemical identity.
Other provisions for the protection of confidentiality.	
Chemical name may be encoded in inventory for 3 years. Specific provisions for protection of confidentiality with respect to other Member States.	Specify procedure for confidentiality claim for chemical identity.
Are there circumstances where confidentiality cannot be claimed?	
Yes. As long as equivalent protection in existence, data will be transmitted to Commission and other Member States. Also a list of non-confidential data.	Specific provisions limit claim for confidentiality for health and safety data. Otherwise only if conditions for non-confidentiality are not met.
Is there a list of non-confidential data?	
Yes: trade name, physico-chemical data, ways of rendering harmless, interpretation of tests, name of testing body, recommended precautions and emergency measures.	No.

	EEC SIXTH AMENDMENT	U.S. TSCA
Is there provision for the disclosure of data?	Yes, to subsequent notifiers if initial notifier agrees and disclosure to Commission and other Member States. No public disclosure.	Yes. A notification must be made available to the public subject to confidentiality.
Can data be shared between different notifiers?	Yes, if agreement between them in writing is produced.	Joint notification is possible but since subsequent manufacturers or importers do not have to submit a notification there is no need for sharing of data.
Is there a requirement for public participation in the system?	No.	Several provisions for public disclosure, public record, disclosure under FOIA and provision that citizens can petition EPA to take action.
Are there listed offences?	No. This is left to Member States. The latter must ensure Directive is carried out. How they ensure that is up to them.	Yes, many are listed.
Is there provision for criminal and/or civil liability?	No, see above.	Provision is made for both criminal and civil liability.

	EEC SIXTH AMENDMENT	U.S. TSCA
What penalties apply to offences?	N/A	Fines up to $25,000, imprisonment up to one year. EPA may also obtain injunctions to restrain violation. Also has search and seizure powers.

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The following include the articles and books cited in this review. Other references have been included for further background information. Almost all references may be found at either the Ontario Ministry of Labour library in Toronto or the University of Toronto law library or science and medicine library.

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APPENDIX I

LEGISLATION AND GUIDELINES

EEC MEMBER STATES

BELGIUM

1) Royal Decree No. 82-1000 To Regulate the Marketing of Substances Which Might be Dangerous for Man or his Environment of May 24, 1982, Moniteur Belge, July 2, 1982, p. 789.

2) Royal Decree of April 9, 1980.

3) Royal Decree of March 19, 1981, Moniteur Belge, March 26, 1981, pp. 3649-3650.

   Noted in IRPTC Bull. 4 : 28 (1981) and Ecochem Bull. No. 183 (May 1981).

DENMARK

1) Chemical Substances and Products Act No. 212 of May 23, 1979.

   Published in (Reference) Int'l Env. Rep. 221 : 4501-4506 (1980) and in condensed form in Int'l Dig. of Health Leg. 30 : 752-756 (1979) and noted in IRPTC Bull. 2 : 13-14 (1979).

2) Amendment Act No. 68 of February 20, 1980.

   Published in (Reference) Int'l Env. Rep. 221 : 4581-4585 (1981) and in condensed form in Int'l Dig. of Health Leg. 31 : 794-795 (1980) and noted in IRPTC Bull. 4 : 21-22 (1981).

3) Statutory Order on Notification of Chemical Substances No. 409 of September 17, 1980.

4) Order No. 540 of September 2, 1982, On Substances and Materials, Lovtidende for Kongeriget Danmark, 1982, Part A, October 16, 1982, No. 81, pp. 1559-1574.

   Published in condensed form in Int'l Dig. of Health Leg. 34 : 124-126 (1983).

5) Registration of Chemicals, a guide booklet published by Denmark's Ministry of the Environment.

FRANCE

1) Chemicals Control Law No. 77-771 of July 12, 1977, Journal Officiel de la Republique Francaise, Edition des Lois et Decrets, July 13, 1977, No. 161, pp. 3701-3703.

   Published in (Reference) Int'l Env. Rep. 231 : 5001-5002 (1978) and in Int'l Dig. of Health Leg. 28 : 975-977 (1977).

2) Decree No. 79-35 of January 15, 1979, 36/NCP/ENV/79.2.

Noted in IRPTC Bull. 2 : 14 (1979).

3) Order of May 28, 1979, 36/NCP/ENV/79.1.

4) Amendment No. 82-905 of October 21, 1982, Journal Officiel de la Republique Francaise, Edition des Lois et Decrets, October 22, 1982, p. 3194.

Published in condensed form in Int'l Dig. of Health Leg. 34 : 128-130 (1983).

5) Safety at Work Law of December 1976.

6) Decree No. 81-278 of March 25, 1981 Establishing an Interministerial Group on Chemical Products, Journal Officiel de la Republique Francaise, Edition des Lois et Decrets, March 27, 1981, No. 73, p. 881.

Noted in Int'l Dig. of Health Leg. 32 : 813 (1981).

7) Instructions of May 31, 1983 On Good Laboratory Practice (GLP) With Regard to Experimental Toxicology, Bulletin Officiel du Ministere des Affaires Sociales et de la Solidarite Nationale et du Secretariat d'Etat Charge de la Sante, July 16, 1983, No. 83/25, Text No. 1065, 16 pp.

Noted in Int'l Dig. of Health Leg. 34 : 868 (1983).

8) Order of June 10, 1983 On the Composition and Working Procedures of the Commission for the Assessment of the Ecotoxicity of Chemical Substances, Journal Officiel de la Republique Francaise, Edition des Lois et Decrets, June 25, 1983, Supplementary Issue No. 146, pp. 5823-5824.

Noted in Int'l Dig. of Health Leg. 34 : 868 (1983).

GERMANY

1) Act on Protection Against Dangerous Substances (Chemicals Act) of September 16, 1980. (Federal Law Gazette (Bundesgesetzblatt) I, p. 1718).

Published in (Reference) Int'l Env. Rep. 241 : 4101-4108 (1981) and in condensed form in Int'l Dig. of Health Leg. 32 : 515-533 (1981).

2) The Chemicals Law Notification and Test Data Ordinance of November 30, 1981. (Federal Law Gazette (Bundesgesetzblatt) I, December 10, 1981, No. 51, pp. 1234-1236).

Published in condensed form in Int'l Dig. of Health Leg. 33 : 893-895 (1982).

3) The Chemicals (Existing Substances) Ordinance of December 2, 1981. (Federal Law Gazette (Bundesgesetzblatt) I, December 10, 1981, No. 51, p. 1239.

Published in condensed form, without Annex, in Int'l Dig. of Health Leg. 33 : 895 (1982).

4) The Chemicals Hazard Designations Ordinance of December 18, 1981. (Federal Law Gazette (Bundesgesetzblatt) I, December 10, 1981, No. 57, pp. 1487-1489.

Published in condensed form in Int'l Dig. of Health Leg. 33 : 895-898 (1982).

GREECE

Legislation regulating new chemicals is not yet in effect.

IRELAND

1) European Communities (Dangerous Substances) (Classification, Packaging, Labelling and Notification) Regulations, 1982. Statutory Instrument No. 258 of 1982.

2) A number of annexes to the S.I. have been published.

ITALY

1) Decree No. 927 of November 24, 1981 of the President of the Republic, Gazzetta Ufficiale della Repubblica Italiana, Part I, February 20, 1982, No. 1982, No. 50, pp. 1280-1923.

Published in condensed form in IRPTC Bull. 5 : 34-35 (1983). Listed in Int'l Dig. of Health Leg. 34 : 623-624 (1983).

2) Circular No. 21 of March 24, 1982, Gazzetta Ufficiale della Repubblica Italiana, Part I, April 1, 1982, Ordinary Supplement to No. 90, pp. 1-142.

Listed in Int'l Dig. of Health Leg. 34 : 624 (1983).

LUXEMBOURG

1) Ministerial Regulations of October 22, 1982 On the Establishment of an Interministerial Committee to Examine Notification Dossiers, Memorial: Journal Officiel du Grand-Duche de Luxembourg, Part A, November 12, 1982, No. 94, pp. 1940-1941.

Published in condensed form in Int'l Dig. of Health Leg. 34 : 319-320 (1983).

NETHERLANDS

1) Chemical Substances Act

2) Interim Decree on the Notification of New Chemical Substances of September 7, 1981, Nederlandse Staatscourant, September 11, 1981, No. 174, p. 7.

Published in condensed form in IRPTC Bull. 5 : 32-33 (1982). Listed in Int'l Dig. of Health Leg. 34 : 624 (1983).

UNITED KINGDOM

1) Health and Safety of Work Act 1974, c. 37.

2) Notification of New Substances Regulations, Statutory Instrument 1982 No. 1496.

3) Approved Codes of Practice
   (i) Principles of Good Laboratory Practice
   (ii) Methods for the Determination of Physico - Chemical Properties
   (iii) Methods for the Determination of Toxicity
   (iv) Methods for the Determination of Ecotoxicity

4) A Guide to the Notification of New Substances Regulations 1982.

OTHER OECD MEMBER STATES

AUSTRALIA

1) Interim Notification Scheme for New Chemicals in Australia. Australian Environment Council, October, 1981.

   A summary of the scheme has been published in IRPTC Bull. 5 : 30 (1982).

2) Discussion Paper on the Proposed National Chemicals Notification and Assessment Scheme. Australian Environment Council, June, 1984..

AUSTRIA

1) Chemicals Law of 1982.

FINLAND

1) Law No. 299 of June 28, 1958 On Occupational Health and Safety.

2) Decree No. 286 of April 20, 1979 On an Identification and Labelling System for Substances Hazardous to Health, Finlands Forfattningssamling, April 25, 1978, Nos. 281-287, pp. 628-631.

   Published in condensed form in Int'l Dig. of Health Leg. 30 : 23-25 (1979).

3) Ordinance No. 492 of June 27, 1980 On Poisons, Finlands Forfattningssamling, July 1, 1980, Nos. 486-494, pp. 1309-1316.

   Published in condensed form in Int'l Dig. of Health Leg. 32 : 288-290 (1981). See also summary in IRPTC Bull. 4: 23-4 (1981) and Ecochem Bulletin No. 170, September 30, 1980.

4) Decree No. 493 of June 27, 1980 On the Poisons List, Finlands Forfattningssamling, July 1, 1980, Nos. 486-494, p. 1317.

   Published in condensed form in Int'l Dig. of Health Leg. 32 : 290 (1981).

5) Ordinance No. 364 of May 21, 1982 amending Sections 20 and 32 of the Ordinance On Poisons, Finlands Forfattningssamling, May 24, 1982, Nos. 360-376, p. 788.

Published in condensed form in Int'l Dig. of Health Leg. 34 : 623 (1983).

ICELAND

1) Law No. 85 of December 31, 1968 On Poisonous Substances and Dangerous Substances, Stjornartidindi, Part A, 1968, No. 18, pp. 331-347.

Published in condensed form in Int'l Dig. of Health Leg. 22 : 470-471 (1971).

2) Order No. 273 of November 3, 1969 On the Poisonous Substances Board, Stjornartidindi, Part B, 1969, No. 10, pp. 454-455.

Published in condensed form in Int'l Dig. of Health Leg. 22 : 475 (1971).

3) Order No. 129 (1971), Notice No. 130 (1971), Order No. 131 (1971), Order 132 (1971), Law No. 27 (1973), Order No. 91 (1974), Order No. 93 (1974), Order No. 455 (1975).

Listed in Int'l Dig. of Health Leg. 29 : 581-582 (1978).

4) Order No. 445 of May 16, 1978 On the Classification of Poisonous and Dangerous Substances, Stjornartidindi, 1978, Part B, February 9, 1979, No. 47, pp. 919-930.

Listed in Int'l Dig. of Health Leg. 31 : 330 (1980).

5) Order No. 349 of August 30, 1978, Amending Order No. 455 of October 14, 1975, Stjornartidindi, 1978, Part B, October 10, 1978, No. 36, p. 735.

Listed in Int'l Dig. of Health Leg. 31 : 330 (1980).

6) Order No. 270 of May 11, 1981, Amending Order No. 445 of May 16, 1978, Stjornartidindi, 1981, Part B, June 30, 1981, No. 29, pp. 443-445.

Listed in Int'l Dig. of Health Leg. 33 : 898-899 (1982).

JAPAN

1) Chemical Substances Control Law, 1973.

2) Enforcement Order of the Chemical Substances Control Law, Cabinet Order No. 202, Promulgated June 7, 1974.

3) Ministerial Order Concerning the Notification, etc., of Manufacture or Import of New Chemical Substances, Order of Minister of Health & Welfare and the Minister of International Trade & Industry No. 1, Promulgated April 15, 1974, Amended June 10, 1974.

4) Customs Clearance Procedures, Issued by the Ministry of International Trade and Industry, July 19, 1974.

5) On the Import of Products Designated by the Enforcement Order of the Chemical Substances Control Law, Issued by the Ministry of International Trade and Industry, July 30, 1974.

6) Interpretation & Application of the Law Concerning the Examination and Regulation of Manufacture, Etc., of Chemical Substances (undated).

7) Distinction Between "Chemical Substances" and "Products" in the Law Concerning the Examination and Regulation of Manufacture, Etc., of Chemical substances, Issued by the Ministry of International Trade and Industry, July 19, 1974.

8) Interpretation of the Items Specified in Article 3 of the Enforcement Order of the Law Concerning the Examination and Regulation of Manufacture, Etc., of Chemical Substances, Issued by the Ministry of International Trade and Industry, July 19, 1974.

9) Order Prescribing the Items of the Test Relating to the New Chemical Substances, Order of the Prime Minister, the Minister of Health & Welfare and the Minister of International Trade & Industry No. 1, Promulgated July 13, 1974.

    a) Method for Testing the Biodegradability of Chemical Substances by Microorganisms

    b) Method for Testing the Degree of Accumulation of Chemical Substances in Fish Body.

    c) General Toxicity Tests, Special Toxicity Tests, Pharmacokinetics Study and General Biological Tests of Chemical Substances

10) Ordinance No. 2 of January 27, 1979 under the Industrial Safety and Health Law, Ministry of Labour.

11) Cabinet Order Designating Aldrin, Dieldrin, Endrin and DDT as Specified Chemical Substances, October 2, 1981.

NEW ZEALAND

1) Toxic Substances Act, 1979, No. 27.

2) Toxic Substances Act Commencement Order 1979, S.R. 1979, No. 276.

3) Toxic Substances Regulation 1983, S.R. 1983, No. 130.

NORWAY

1) The Product Control Act No. 79 of June 11, 1976.

2) Worker Protection and the Working Environment Act of February 4, 1977, Norsk Lovtidend, Part I, February 14, 1977, No. 4, pp. 77-108; as amended by Law No. 52 of June 3, 1977, Norsk Lovtidend, Part I, June 16, 1977, No. 17, pp. 465-490 and by Law No. 32 of May 26, 1978, Norsk Lovtidend, Part I, June 16, 1977, No. 16, p. 336.

A condensed version has been published in Int'l Dig. of Health Leg. 30 : 109-111. See also ILO Legislative Series 1978, No. 1 and ILO Social Labour Bull., 1977, No. 3, pp. 233-237.

3) Regulation No. 1635 Concerning Labelling, Sale Etc. of Chemical Substances and Products Which May Involve a Hazard to Health, Royal Decree of November 26, 1982.

Published in condensed form in Int'l Dig. of Health Leg. 34 : 320-321 (1983); summary published in IRPTC Bull. 5 : 29 (1982).

4) Text of October 7, 1977, Norsk Lovtidend, Part I, October 24, 1977, No. 30, p. 847.

Noted at Int'l Dig. of Health Leg. 30 : 111 (1979).

5) Amendments No. 1428 of September 1, 1982, Norsk Lovtidend, Part I, October 14, 1982, No. 21, pp. 495-496.

Noted in Int'l Dig. of Health Leg. 34 : 320 (1983).

PORTUGAL

No indication of legislation on notification of new chemicals.

SPAIN

No indication of legislation on notification of new chemicals.

SWEDEN

1) Act on Products Hazardous to Health and to the Environment, Swedish Code of Statutes, 1973 : 329.

2) Ordinance on Products Hazardous to Health and to the Environment, Swedish Code of Statutes, 1973 : 334.

3) Ordinance Giving Directions on the Reporting of Certain Products, SNFS, 1978:2PK:4.

SWITZERLAND

1) Federal Law on Trade in Toxic Substances (Toxicity Law) of March 21, 1969.

2) Order on Prohibited Toxic Substances of December 23, 1971.

3) Implementing Order for the Federal Law on Trade in Toxic Substances of December 23, 1971.

4) Federal Law on Environment Protection of October 7, 1983.

TURKEY

No indication of legislation on notification of new chemicals.

UNITED STATES

1) Toxic Substances Control Act 15 U.S.C. 2601-2629 (1976).

2) Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures, Federal Register, Vol. 48, No. 94, May 13, 1983.

3) Premanufacture Notification; Revision of Regulation and Partial Stay of Effective Date, Federal Register, Vol. 48, No. 178, September 13, 1983.

YUGOSLAVIA

1) Poisons Trade Act of July 15, 1982, Official Gazette of the SFRY, No. 43/82.

2) Regulations on Destruction of Unused Poisons and Containers thereof, and on Poisons Withdrawal.

3) Regulations on More Specific Criteria for Classifying Poisons and on Methods for Determining Degree of their Toxicity.